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—Preliminary Instructions—

1 PROCEEDINGS had before The Honorable Irene C. Berger,
2 Judge, United States District Court, Southern District of West
3 Virginia, in Charleston, West Virginia, on November 03, 2014,
4 at 9:00 a.m., as follows:

5 THE COURT: Good morning, everyone.

6 Ladies and gentlemen, I have some pre-trial
7 instructions that I want to give you this morning before we
8 begin the trial.

9 You have been selected as jurors and have taken an
10 oath to well and truly try this case. And as I've indicated
11 to you, I expect the trial to last approximately ten and a
12 half working days.

13 During the trial, there will be times, as you know,
14 that I will take breaks or recesses. During those times, you
15 must not talk about this case among yourselves or with anyone
16 else.

17 Further, you are instructed not to permit anyone to
18 discuss the case in your presence. This instruction goes to
19 your family and friends as well.

20 It is your sole and exclusive responsibility in the
21 case to decide the case solely upon the law and evidence
22 without help and assistance from persons other than your
23 fellow jurors.

24 You will find yourselves together in the jury room in
25 the mornings before trial, in the afternoon after lunch, and

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1 at various other times. Even though you are all together,
2 you're not to discuss this case until I release you to
3 deliberate your verdict at the conclusion of the case.

4 Further, you are instructed not to conduct any
5 independent investigation or research the facts and
6 circumstances of the facts or research the law related to the
7 case, nor are you to use a dictionary, computer, or other
8 reference materials including but not limited to Bing, Google,
9 or any other research tool to define terms or gain knowledge
10 about issues or people, including the lawyers, which you hear
11 about during the course of this trial.

12 You may not communicate with anyone about the case on
13 your cell phone, through e-mail, Blackberry, text messaging,
14 or on Twitter, through any blog or website, through any
15 internet chat room, or by way of any other social networking
16 websites, including but not limited to Facebook, Myspace,
17 LinkedIn, and YouTube or, of course, by any other means.

18 Until you retire to deliberate, you may not discuss
19 the case, again, with anyone, even your fellow jurors.

20 After you retire to deliberate, you may begin
21 discussing the case with your fellow jurors, but you cannot
22 discuss the case with anyone else until you have returned a
23 verdict and the case is at an end. You must also keep each
24 other honest. Therefore, I will expect you to inform me if
25 you become aware of a juror violating these instructions.

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1 You may take notes. On your chairs you have found
2 notepads and pens. Your notes are not evidence and should not
3 take the place of listening to or watching witnesses.

4 Do not rely on someone else's notes or recollections.
5 When you leave the courtroom, place your notepads face down.
6 No one will look at them and the room will be secured each
7 night.

8 You're further instructed not to take any photographs
9 or videos with your cell phones of fellow jurors or of any
10 part of the court proceedings.

11 During the trial, do not talk to any of the
12 plaintiffs or defendants or lawyers or any of the witnesses.
13 As I told you on Friday, if you see any of the parties seated
14 at counsel table on the elevator or outside on the sidewalk
15 and say "good morning" to them, they are likely to shy away
16 from you. That's not intended as any arrogance or
17 unfriendliness on their parts. They are simply trying to keep
18 my instruction that they stay clear of you ladies and
19 gentlemen as well.

20 If anyone tries to talk to you about any of the
21 matters under consideration in this trial, you should
22 immediately report that to me or to the court security
23 officer.

24 There will be people meeting in other rooms while you
25 all are in the jury room. So, be sure to keep your jury room

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1 door closed whenever possible. If you hear anything about the
2 case while you're in the jury room, be sure to let me know.

3 It is a Judge's responsibility to preside over a
4 trial impartially and without favor to either side. So, while
5 judges may exhibit certain attitudes or may make rulings for
6 one side or another in any given situation, you should not
7 take this in any way as any indication that the Judge wishes
8 you to reach a certain result in the case.

9 You should keep an open mind. You should not form or
10 express a final opinion on any issue during the trial. You
11 should keep from reaching a conclusion on the case until you
12 have heard all of the evidence, the arguments of the
13 attorneys, and the final instructions on the law that I will
14 give to you after you have heard all of the evidence.

15 You must not permit yourself to be influenced by
16 sympathy, bias, passion, or favor as to either side.
17 Remember, you have a duty to discuss the case with your fellow
18 jurors during deliberations prior to reaching a conclusion in
19 the case.

20 This is a consolidated trial of four separate cases
21 filed by four separate plaintiffs against Boston Scientific.
22 Although the evidence will be presented in one trial together
23 and although some evidence may overlap, you must consider each
24 plaintiff and her individual claims separately from the
25 others. That is, treat each case separately as if each have

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1 been tried by itself.

2 In that regard, you may not consider facts that
3 relate specifically to only one plaintiff as to any other
4 plaintiff. You may not even consider that more than one claim
5 was brought when reaching your verdict as to a particular
6 plaintiff.

7 Likewise, as to Boston Scientific's defenses, you
8 must consider its defenses separately with respect to each
9 plaintiff.

10 At the end of the trial, you will be asked to decide
11 each of the cases separately, and your decision for each case
12 must rest on the merits of each plaintiffs' individual claims
13 and on the merits of Boston Scientific's defenses as to each
14 plaintiffs' claims.

15 You ladies and gentlemen as jurors are the judges of
16 the facts. You must apply the facts as you find them to the
17 law as I will give it to you in these instructions and in
18 later instructions.

19 In a civil case such as this, the plaintiff has the
20 burden of proving each and every element of her case by a
21 preponderance of the evidence. To prove by a preponderance of
22 the evidence means to prove that something is more likely so
23 than not so.

24 When more than one claim is involved and when more
25 than one defense is asserted, you should consider each claim

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1 and defense separately. But in deciding whether any fact has
2 been proven by a preponderance of the evidence, you may
3 consider the testimony of all of the witnesses, regardless of
4 who may have called them, and all exhibits received in
5 evidence, regardless of who may have produced them.

6 You must base your verdict solely upon the evidence
7 presented in the case. The evidence consists of the sworn
8 testimony of the witnesses, the exhibits, stipulations, and
9 those matters of which I take judicial notice.

10 When the parties stipulate or agree that a fact is
11 true, you may consider the fact to be true. During the trial
12 I may take judicial notice of a fact. You may consider that
13 fact to be true.

14 Many of you raised your hands when I asked about
15 television commercials related to pelvic mesh. Understand
16 that the fact that lawyers are advertising on television for
17 pelvic mesh cases or even the fact that there are more pelvic
18 mesh claims being made is not evidence whatsoever. You shall
19 not consider any of this in your deliberations in this case.

20 The defendant has been brought to trial only for the
21 claims made by the plaintiffs in this lawsuit. Therefore,
22 each plaintiff in this case has the burden of proving that the
23 particular product in this -- the Obtryx was defectively
24 designed and not accompanied by adequate warnings. You may
25 not speculate about the existence or nonexistence of other

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1 claims or the merits or demerits of any such claim.

2 I may instruct you that evidence can only be used for
3 a limited or particular purpose. Consider any evidence
4 admitted for a limited purpose only for that limited purpose.

5 Now, I will instruct you on how to view some of the
6 events that are likely to occur during the trial.

7 Initially, ladies and gentlemen, the attorneys will
8 have an opportunity to make opening statements. Counsel for
9 the plaintiffs will make an opening statement first. Then
10 counsel for the defendant may, but does not have to, make an
11 opening statement.

12 These statements should be considered only as a
13 preview of what the attorneys expect the evidence in the trial
14 to be. These statements are not evidence.

15 Next, witnesses will be called to testify. They will
16 be placed under oath and questioned by the attorneys. First,
17 counsel for the plaintiffs will present witnesses through
18 direct examination, and counsel for the defendant can
19 cross-examine them if there is cross-examination. Then
20 counsel for the plaintiffs will have an opportunity to
21 redirect the witnesses.

22 At the conclusion of the plaintiffs' case, counsel
23 for the defendant may, but is not required to, call witnesses.
24 Counsel for the plaintiffs will have the opportunity to
25 cross-examine those witnesses. If that occurs, counsel for

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1 the defendant will conduct redirect examination if he or she
2 chooses.

3 You, ladies and gentlemen of the jury, will determine
4 the credit and weight you will give to the testimony of each
5 witness. In doing this, you can consider, if found by you
6 from the evidence, his or her good memory or lack of memory;
7 his or her interest or lack of interest in the outcome of the
8 trial; the intelligence or lack of intelligence of the
9 witness; his or her demeanor and manner of testifying; his or
10 her opportunity and means or lack of opportunity and means of
11 having knowledge concerning the matters which he or she
12 testifies; the bias, prejudice, hostility, friendliness or
13 unfriendliness of the witness for or against any of the
14 parties; the relationship of any witness to any of the parties
15 or other witnesses; the reasonableness or unreasonableness of
16 the witness's testimony; and his or her apparent fairness or
17 lack of fairness.

18 At times witnesses may appear by deposition testimony
19 read to you from a written transcript or shown by videotape
20 recording consisting of answers under oath to questions asked
21 of the witness in advance of the trial in the presence of a
22 court reporter. These depositions are taken out of the
23 presence of the Court.

24 The testimony of a witness who for some reason cannot
25 be present to testify from the witness stand is entitled to

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1 the same consideration and is to be judged as to credibility
2 and weight as if the individual had been present and had
3 testified here from the witness stand.

4 Also, during the trial I might receive documents and
5 other exhibits as evidence. If evidence is given to you to
6 examine, you should examine it carefully without comment and
7 remember that you will have another opportunity to examine the
8 evidence during the course of your deliberations.

9 You should also know that it is an attorney's right
10 and duty to object when testimony or other evidence is being
11 offered that he or she believes should not be admitted into
12 evidence. When I decide that an objection is correct, I will
13 sustain it and you should act as if you never saw the evidence
14 or heard the attorney's question or the witness's answer if
15 given.

16 There also may be times when I will strike evidence
17 from the record. You should act as if this evidence never
18 existed.

19 However, if I decide that an objection is not
20 correct, I will overrule it and you should give that evidence
21 no more or less weight than if the objection had not been
22 made.

23 Sometimes an attorney will request a bench conference
24 or a recess to discuss an objection. That's not intended to
25 hide or conceal anything from you ladies and gentlemen of the

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1 jury. But it is designed to ensure that only relevant and
2 legally admissible evidence is presented in your presence.

3 There may be times that I will refuse a bench
4 conference or recess and you should draw no inferences from
5 that whatsoever.

6 Finally, the attorneys will make closing arguments.
7 These arguments, like opening statements, are not evidence.
8 The attorneys at this time are permitted to summarize the
9 evidence and the law and try to persuade you to decide on a
10 particular verdict.

11 You as jurors may accept or reject these arguments as
12 you see fit. If any argument, statement, or remark of counsel
13 is not consistent with the evidence or with my instructions on
14 the law, then you should disregard that argument, statement,
15 or remark.

16 I'm going to give you detailed instructions on the
17 law at the end of the case. But in order to help you follow
18 the evidence, I will give you a brief summary of what each of
19 the plaintiffs must prove to make their case in connection
20 with each cause of action.

21 The plaintiffs have claims for strict liability for
22 design defect, strict liability for failure to warn, and
23 negligence.

24 Also, one of the plaintiffs' spouses -- one of the
25 plaintiffs' spouse has a claim for loss of consortium. I will

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1 give you a brief overview of these claims.

2 The defendant, Boston Scientific, denies these
3 claims.

4 The plaintiffs contend that they were each injured as
5 a result of implantation of the defendant's product, the
6 Obtryx. The plaintiffs' first claim is that the Obtryx was
7 defectively designed. To recover damages for a defectively
8 designed product, a person injured by the allegedly defective
9 product must establish the following elements by a
10 preponderance of the evidence:

11 First, that the allegedly defective design conditions
12 existed in the Obtryx product at the time it left the control
13 of Boston Scientific; that the allegedly defective conditions,
14 secondly, made the Obtryx not reasonably safe for its intended
15 use; third, that the plaintiff was injured; and, fourth, that
16 the plaintiffs' injuries were proximately caused by the
17 allegedly defective conditions of the Obtryx.

18 The proximate cause of an injury is the last
19 negligent act contributing to the injury and without which the
20 injury would not have occurred. Proximate cause must be
21 understood as that cause which in actual sequence unbroken by
22 any independent cause produced the event without which such
23 event would not have occurred.

24 I will explain what, quote, "not reasonably safe for
25 its intended use" means at the end of this trial.

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1 The plaintiffs also bring a claim in strict liability
2 for failure to warn. The plaintiffs contend that the Obtryx
3 sling was not reasonably safe for its intended use because it
4 lacked adequate warnings. Because the Obtryx can only be
5 obtained through a physician, the defendant had a duty to
6 adequately warn only the physicians who implant the Obtryx.

7 The defendant did not have a duty to warn consumers
8 such as the plaintiffs. Any evidence or argument that Boston
9 Scientific owed a -- or breached a duty to warn the plaintiffs
10 directly is improper and it may not be considered in reaching
11 your verdict.

12 To recover damages for failure to warn and strict
13 liability, a plaintiff must establish the following elements
14 by a preponderance of the evidence:

15 First, that the defendant failed to provide adequate
16 warnings to the plaintiffs' physician; secondly, that the lack
17 of adequate warnings made the Obtryx not reasonably safe for
18 its intended use; third, that the plaintiff was injured; and,
19 fourth that the plaintiffs' injuries were proximately caused
20 by the lack of adequate warnings to the plaintiffs' physician
21 by the manufacturer.

22 The plaintiffs have also made a claim for negligence.
23 Broadly, defendants had a duty to use ordinary care for the
24 plaintiffs' safety. Negligence means the failure of a person
25 to use due care or to do something that a reasonable and

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1 prudent person would do in the same or similar circumstances.

2 On the other hand, negligence may be the doing of
3 something that a reasonably prudent person would not do in the
4 same or similar circumstances. The plaintiff, plaintiffs
5 allege that the defendant was negligent in two ways.

6 First, the plaintiffs allege that the defendant was
7 negligent in its design of the Obtryx. To recover damages as
8 a result of negligent design, a plaintiff must prove by a
9 preponderance of the evidence that Boston Scientific was
10 negligent and that that negligence was the proximate cause of
11 the plaintiffs' injuries.

12 The plaintiffs' second theory of negligence is that
13 the defendant was negligent in failing to provide adequate
14 warnings. You should remember that the defendant did not have
15 a duty to warn consumers such as the plaintiffs but, instead,
16 had a duty to warn their physicians as learned intermediaries.

17 To recover damages as a result of negligent failure
18 to warn, a plaintiff must prove by a preponderance of the
19 evidence Boston Scientific was negligent and such negligence
20 was the proximate cause of the plaintiffs' injuries.

21 For both negligence claims, proximate cause is that
22 cause which in actual sequence unbroken by an independent
23 cause produced the wrong complained of without which the wrong
24 would not have occurred.

25 The proximate cause of an injury is the last

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1 negligent act contributing to the injury and without which the
2 injury would not have occurred.

3 Additionally, Mr. Tyree brings a claim for loss of
4 consortium. Consortium is a right arising from the marital
5 union to have performance by a spouse of all the duties and
6 obligations assumed by the marriage relationship including the
7 right to society, companionship, and services.

8 As I've indicated to you on Friday, ladies and
9 gentlemen, do not read any newspaper accounts or listen to any
10 radio or view or listen to any television or internet coverage
11 that there might be of the trial. You are instructed to
12 completely disregard such information and decide the issues
13 solely on the basis of the facts and law presented to you here
14 in this courtroom.

15 To help ensure that your decision is based only on
16 the law and the facts, the jury room door should remain closed
17 at all times. For your planning, I believe I indicated to you
18 on Friday we will generally begin court at 9:00 a.m. and
19 conclude somewhere as close to 5:00 in the evening as we can.

20 If at any time during the course of the trial you
21 become tired or have difficulty hearing or seeing or
22 experience any discomfort such that it is necessary to take a
23 break, please feel free to raise your hand.

24 At this point, ladies and gentlemen, you will hear
25 the opening statements that I referred to here in these

Opening Statement - Mr. Love

1 instructions after you take your oath.

2 (Jury panel sworn)

3 THE COURT: Counsel for the plaintiff, will you go
4 forward with opening?

5 MR. LOVE: We're ready to proceed, Your Honor.

6 THE COURT: Mr. Love.

7 MR. LOVE: Your Honor, I've been requested to ask you
8 to turn on the main monitor.

9 THE COURT: All right. Did I do it?

10 MR. LOVE: You did, ma'am.

11 THE COURT: Thank you.

12 MR. LOVE: May I proceed, Your Honor?

13 THE COURT: Yes, sir.

14 MR. LOVE: Good morning.

15 You and I haven't been properly introduced. My name
16 is Scott Love. And on behalf of my colleagues, Paul Farrell,
17 Aimee Wagstaff, and Doug Monsour, we have the pleasure to
18 represent these four fine ladies here, Jacquelyn Tyree, Carol
19 Campbell, Jeanie Blankenship, and Chris Wilson.

20 You're going to get to hear their story as this trial
21 develops. You're going to get to hear how their lives have
22 been impacted by the Obtryx sling.

23 And this is a pretty simple case. My clients
24 experienced a pretty common condition called stress urinary
25 incontinence. And you're going to hear quite a bit about that

Opening Statement - Mr. Love

1 throughout the course of this trial.

2 This company here made a product called the Obtryx
3 sling that was supposed to help, but didn't.

4 Boston Scientific, you may ask: What do they do? As
5 you might suspect, they're a company that's located right
6 outside of Boston, Massachusetts. This is a medical device
7 company, one of the ten largest in the world that makes
8 medical devices, many of which are for women's issues.

9 This company, in addition to some of the other
10 products, they made the Obtryx sling. They made it to treat
11 what's called stress urinary incontinence.

12 Now, the textbook definition of stress urinary
13 incontinence is the uncontrollable leakage of urine during
14 physical activities such as coughing, sneezing, lifting,
15 laughing, or exercising.

16 This condition primarily afflicts women, and it
17 primarily afflicts women who have had children. And as you
18 might suspect, as we all get older and as we age, we tend to
19 get wrinkles under the eyes, gray hair, our bellies get
20 bigger.

21 Well, your internal organs age just like the outside
22 of you does. Sometimes your body parts internally droop.
23 Sometimes you lose some of the support that you have in
24 different body parts.

25 Well, what stress urinary incontinence is, it is the

Opening Statement - Mr. Love

1 loss of adequate support from the urethra that's right above
2 the bladder. And, so, when that support is lost, as women
3 age, the urethra doesn't close properly and you get leakage.

4 It's an embarrassing condition. It can be
5 uncomfortable. But there are many effective ways to treat
6 this condition. Exercise is one such option that women have
7 available to them. Medications are available. Pads or
8 diapers are available. And there are also surgical options.
9 And there are many different types of surgical options that
10 can treat this condition.

11 Boston Scientific made the Obtryx sling. Each of my
12 clients has the Obtryx sling. And there are essentially four
13 component parts to the Obtryx sling. And that's the kit
14 you're looking at there.

15 There are these two big hook-like devices. These are
16 called trocars. And you're going to hear a lot about trocars
17 throughout the course of the trial.

18 There's also this mesh. And you're going to hear a
19 lot about the mesh. And essentially -- I'm no doctor. You're
20 going to hear from some smart medical people that are going to
21 tell you exactly how this product works. But just from a
22 conceptual standpoint, the idea behind the mesh is that it is
23 inserted transvaginally with these hooks and that it is
24 supposed to reinforce and provide support for the urethra
25 that's been lost over time. And, so, the urethra will close

Opening Statement - Mr. Love

1 and the leakage will stop.

2 Now, this product is supposed to be put in once,
3 once. It's a permanent implant. It's intended to be in the
4 body for life. It's intended to fix the problem for life.

5 And this mesh here -- and not all this mesh goes in.
6 But essentially what they do is once they get it inside, they
7 clip it. And there's a portion there that's used to support
8 the urethra.

9 So, what went wrong? In each of these cases, this
10 product didn't work. In each of these cases, each of my
11 clients has had to have a second or third surgery to fix the
12 problems caused by this product or have it removed.

13 And the consequences for each of my clients is severe
14 and life-long. And, most importantly, the consequences were
15 avoidable. They were avoidable if this company would have
16 done its job.

17 This is really a case about lost trust. My clients
18 trusted that they were getting a product that had been tested
19 and was safe. That may seem illogical. Right? A company
20 makes a product that's going to be put in your body for life.
21 You would expect it to be tested in humans and establish it's
22 safe before they started selling it to women.

23 My clients trusted that they were being told the
24 truth about the dangers of this product and what this company
25 really knew about the product. In both cases, this company

Opening Statement - Mr. Love

1 failed my clients.

2 You're going to hear over the course of this trial
3 that they never tested this product in humans to make sure it
4 was safe before they began selling it. It is undisputed.
5 There will be no lawyer, no witness, no expert to come in from
6 their side to say, "We did human testing on this product."

7 You're going to hear that they didn't give the full
8 truth about the dangers of this product and what they really
9 knew about the properties that comprise this product.

10 As you go through the evidence over the course of
11 this trial, there are a couple of guiding principles that will
12 help you evaluate the evidence. Now, these aren't
13 controversial in any respect. You're not going to hear Boston
14 Scientific's lawyers get up and say they don't agree with
15 these rules. But these rules will help guide you as you
16 evaluate the evidence that's presented to you over the course
17 of this trial.

18 First rule: It's Boston Scientific's responsibility
19 to make sure its products are safe for women. You're going to
20 hear their employees say, "Yes, it's our responsibility. It's
21 our product. It's our profits. And it's our responsibility
22 to make sure they're safe before they begin selling them."

23 The second rule: It is Boston Scientific's
24 responsibility to adequately warn physicians about the risks
25 that are known or knowable about their products. That makes

Opening Statement - Mr. Love

1 sense too. Right?

2 You have doctors that are using this, surgeons that
3 are using this product all over the country and they've got
4 choices. They can choose other products. And it's Boston's
5 responsibility to make sure these doctors are making informed
6 decisions for their patients so that they have good outcomes.

7 So, how does a company like Boston Scientific warn?
8 There are a number of different ways, but the principal way is
9 with the Directions for Use. And I said there were four
10 component parts to this Obtryx sling kit, and those are three.
11 The fourth is the instruction manual. And this accompanies
12 every product that's sold to surgeons.

13 And it's used primarily by surgeons for a couple of
14 things. One, it tells them how to use the product. How do I
15 use it safely?

16 And, second, and most important, it tells about the
17 dangers associated with this product. It tells them about
18 what does this company know that might be useful to a
19 physician in making a decision about a product.

20 At the end of the day, the goal of this Directions
21 for Use is to allow a doctor and a patient to have an honest
22 conversation about choices because at the end of the day when
23 you go into a doctor's office and you have to have a permanent
24 implant, you want to have an honest conversation. You want to
25 know the full truth so that if you make a decision knowing the

Opening Statement - Mr. Love

1 full truth and something bad happens, we're not here.

2 But if you're not told the full truth, if you're not
3 given all of the information, the doctor and patient can't
4 have an honest conversation. They can't choose which product
5 is best for this particular patient.

6 We've all seen these shows *CSI, Crime Scene*
7 *Investigation. Cold Case* is another one. And there are a lot
8 of things about those shows that aren't really realistic. But
9 there's a couple of things that are really, really important
10 that happen that are relevant here.

11 And take *Cold Case*, for instance. *Cold Case* is that
12 show where they're investigating cases that occurred years and
13 years ago. And what happens at the beginning of every one of
14 those shows? You see detectives going out of the evidence
15 room and getting boxes and boxes of documents and witness
16 statements, documents that were created at the time the events
17 were occurring.

18 And from there, what they do is they put together a
19 story. They figure out what the witnesses saw, what they
20 heard, what they did, the decisions they made. They get to
21 see documents that were created at the time the events were
22 unfolding, and they put together the truth. They figure out
23 what happened.

24 Well, your investigation in this case is no
25 different. You're going to see different types of evidence

Opening Statement - Mr. Love

1 presented to you over the course of this trial. You're going
2 to get to see testimony from the Boston Scientific employees,
3 the people that were there that were making the decisions to
4 test or not test, that were making the decisions what to
5 include in the Directions for Use. You're going to get to see
6 the internal documents that were created as these events were
7 unfolding. And these documents and these employees are going
8 to lead you to the truth.

9 There is no more important evidence in this case than
10 those two things. The only people that really know the truth
11 are the people that were there and the documents that were
12 created at the time the events were unfolding.

13 Now, you're also going to hear from medical witnesses
14 as well as doctors. They're going to talk to you about these
15 ladies' injuries. You're also going to hear from experts.
16 I've got experts. They've got experts. I hope you find my
17 experts helpful. I think that in cases like this experts can
18 be helpful on certain types of issues, and I hope you find
19 mine credible. But at the end of the day, it is the employees
20 that are going to tell us what the truth is.

21 Now, Rob Adams, my opposing counsel for Boston
22 Scientific, we've been working on this case for two or three
23 years together and his team. You're going to like him. I
24 like him. But he was hired about seven years too late to fix
25 a problem that's not fixable.

Opening Statement - Mr. Love

1 You're going to hear that from this company's
2 perspective it's about winning. Remember that phrase. It's
3 about winning. You're going to hear that when this product
4 first came on the market, it was about winning and gaining
5 market share and not about safety. In this courtroom for this
6 company it's about winning, irrespective of the truth.

7 At the end of the day, though, when you push aside
8 the lawyers, when you push aside the experts that we've hired,
9 and you want to know the truth, you're going to hear it from
10 Boston Scientific's employees' lips. These guys are going to
11 tell you the truth.

12 And these guys just aren't low-level employees by any
13 means. These are, these are at the top of the chain of
14 command; Vice President of Regulatory Affairs, Vice President
15 of Global Marketing, Vice President of Research and
16 Development. You're hearing it from the bigwigs. Listen to
17 their admissions. Listen to what they admit to. Listen to
18 what they knew and the decisions that they made.

19 Now, the Judge at some point in this trial may talk
20 to you about credibility. And it's your job to judge
21 credibility; credibility of the witnesses, credibility of the
22 evidence, my credibility. I hope over the course of this
23 trial you find me credible, you find us credible.

24 But at the end of the day when you're listening to
25 the lawyers argue, when you're listening to experts that have

Opening Statement - Mr. Love

1 been hired by the lawyers state their opinions, compare it to
2 what the employees admit to and then listen to their
3 arguments.

4 Are my arguments consistent with what they're going
5 to tell you? Are my arguments -- are their arguments
6 consistent or inconsistent with what you're going to hear?

7 Now, over the course of this trial you're going to be
8 asked to answer three essential questions. And the Judge just
9 summarized them for you.

10 The first is: Did Boston Scientific give physicians
11 adequate warnings about the known dangers and those dangers
12 which were knowable? Did they allow the physicians in these
13 cases to make informed decisions? That's the first question.

14 Second question: Was the Obtryx sling defective?
15 Was it made to be in humans? Remember that mesh. You're
16 going to hear a lot about the mesh. Was the mesh fit to be in
17 humans? You're going to have to answer the question.

18 And, last, the question you're going to have to
19 answer is: How did these women suffer? What is their life
20 today like? What have they been through over the course of
21 the last five, six, seven years?

22 You remember I told you about that first
23 responsibility. Make sure your products are safe. You're
24 going to hear from Evan Brasington. He's the Vice President
25 of Global Marketing.

Opening Statement - Mr. Love

1 Now, Mr. Brasington is going to tell you that when
2 you introduce new products for sale, they need to be supported
3 by reliable research. He's going to tell you that. That's
4 common sense. But he's going to say, "Yeah, when you
5 introduce a new product, it needs to be supported by science
6 so people are safe."

7 Then you're going to hear from Rob Miragliuolo, the
8 Vice President of Regulatory Affairs. He's going to say,
9 "Even though we knew that, we did no human studies on this
10 product prior to selling it."

11 You're also going to -- you may ask yourself, "Well,
12 how in the heck -- how can a company make a product and ensure
13 that it's safe with no human testing?" It can't. They know
14 what the rules are.

15 Evan Brasington is going to tell you, "The rule is
16 we've got to make safe products and we've got to have solid
17 research." But they broke their own rules.

18 You're also going to hear from a gentleman named
19 Charles Smith. He's the Director of Development. And you're
20 going to hear from Charles Smith that in January of 2004, the
21 people who make this mesh, Chevron Phillips, you're going to
22 hear, make the mesh that go under that supports the urethra,
23 that Chevron Phillips who was selling the resin to them, the
24 little plastic pellets you're going to hear that ultimately
25 are manufactured into this mesh product, you're going to hear

Opening Statement - Mr. Love

1 from Charles Smith that in January of 2004 Chevron Phillips
2 said, "Don't use this product for permanent implantation in
3 the human body."

4 He's going to tell you again in 2007 they told him
5 the same thing. So, before they began selling this product,
6 you're going to hear from their lips that, "We were told not
7 to sell it." And even with that knowledge, they did no human
8 testing.

9 You're also going to hear from a lady named Doreen
10 Rao who was one of the principal engineers on the mesh project
11 that became the Obtryx sling. You're going to hear from her
12 live, and I believe you'll hear from her tomorrow.

13 She's going to say, "While we didn't do human
14 testing, we did some other testing in the laboratory." And
15 they did. But you're also going to hear that some of that
16 laboratory testing failed. And, yet, they didn't follow up
17 with human testing.

18 And, finally, you're going to hear from a gentleman
19 named Alex Robbins. And you're going to hear that Mr. Robbins
20 is involved in training key opinion leaders or doctors,
21 training these doctors to go out and promote Boston
22 Scientific's products.

23 You're going to hear that Mr. Robbins trains sales
24 reps nationally. And you're going to hear that the global
25 training manager for this company sought out his advice on a

Opening Statement - Mr. Love

1 study that the company had done that didn't turn out well.

2 And you're going to hear from Mr. Robbins in his
3 e-mail that he said, "Don't send it to physicians. This won't
4 help us selling our product."

5 Boston may argue that, "Listen, guys, there was
6 plenty of testing on mid-urethral slings in humans." And
7 you'll hear over the course of trial that the Obtryx sling is
8 part of a group of slings that other companies make called
9 mid-urethral slings. And you'll hear that there's some
10 different versions of those. And they're going to say, "Well,
11 gosh, we have tons and tons of studies on other products."
12 Not on this product.

13 Boston Scientific made specific design changes that
14 were different, made it different from any other product on
15 the market, and they did no human testing.

16 You're going to hear evidence that they were given a
17 new warning before this product was ever sold and still did no
18 human testing.

19 Testing on other products done by other companies
20 can't establish that this product is safe because it was
21 different.

22 I've seen Boston Scientific use this slide and argue
23 that, "Listen, look at all the studies that were done on
24 Obtryx. Look at all these Obtryx studies that were done."

25 Start in 2006 and look at -- and you'll see what

Opening Statement - Mr. Love

1 these names are. These names are -- typically, studies are
2 done by a bunch of different scientists. And, so, what we
3 typically do is we refer to a study by the last -- the first
4 scientist's last name.

5 So, if you look, for instance, in 2008 Gamble.
6 That's called the Gamble study because that's the first
7 scientist. And you may hear them say, "Look at all these
8 studies that were done."

9 I'll just say this about this slide for now.
10 Remember it. Remember this slide. I challenge Boston
11 Scientific to put this slide up and suggest to you that these
12 are all --

13 MR. ADAMS: Objection, Your Honor. This is argument.
14 This is not talking about evidence.

15 THE COURT: The objection to that portion of your
16 statement that began with "challenge" is sustained, Mr. Love.

17 MR. LOVE: Okay, sure. Thank you, Your Honor.

18 THE COURT: Yes, sir.

19 MR. LOVE: Now, with respect to this slide, if it's
20 suggested in evidence that these Obtryx studies established
21 that the product is safe, there's going to be fireworks
22 because it's not the truth.

23 The truth is it's not until 2009, five years after
24 this product is made available for sale, that this company
25 does its first study, its first randomized controlled trial in

Opening Statement - Mr. Love

1 humans. And it's called the Ross study. The first study this
2 company does five years after it begins to sell it to humans
3 is the Ross study. And the results of the Ross study are
4 disastrous.

5 Dr. Sue Ross was the lead author in this particular
6 study. You'll hear that in evidence that she is a paid
7 consultant for this company; that she was hand-picked by
8 Boston Scientific to perform this study. And you'll hear that
9 the study was comparing the Obtryx sling versus another sling
10 called the TVT Advantage. So, they were comparing
11 head-to-head which one's better, the TVT or the Obtryx.

12 And this is the last sentence in her study. This is
13 what she tells the reader. "Until long-term studies are done,
14 until long-term follow-up is available, the TVT should remain
15 the mid-urethral sling procedure of choice."

16 So, Boston finally gets around to doing its own study
17 and their own consultants say, "Don't use the Obtryx."

18 The rules say it is Boston Scientific's
19 responsibility to warn. Here's the tragedy. Three of my
20 clients had their surgery after this study was published.

21 Here's the other tragedy. Boston Scientific never
22 updated the Directions for Use to make sure that this
23 information was in this Directions for Use so that doctors
24 could sit down with their patients and have honest
25 conversations, so that they could make informed decisions, so

Opening Statement - Mr. Love

1 that a patient can sit down and that the doctor can say,
2 "Listen, we've now got study results for the Obtryx. We've
3 got one product that has been tested and it seems relatively
4 safe. And then we've also got the Obtryx. But the Obtryx,
5 however, you know, the scientist that did it recommends to use
6 a different product. So, let's make an informed decision and
7 a decision that's best for you."

8 That decision was taken away from my clients. Think
9 about the conversation they could have had if they had known
10 the truth.

11 Now, Boston may argue that, "Listen, we did
12 biocompatibility testing. We did bench testing." You'll hear
13 about bench testing. Here's the problem. You can't establish
14 that a product is safe in humans by doing just this testing.
15 This is the first step in a long line of testing that has to
16 be done when you're making products that are going to be
17 permanently implanted in the human body.

18 You're going to hear from Doreen Rao who was in
19 charge of some of that bench testing. And she's going to say
20 some of those tests failed.

21 You're going to hear from Rob Miragliuolo, the Vice
22 President of Regulatory Affairs, say, "Listen, we know that
23 you've got to test in the environment where the product is
24 going to be used." Right? Makes sense. If you're going to
25 permanently implant it in the pelvic region of a woman, you've

Opening Statement - Mr. Love

1 got to test it there. You've got to make sure it's going to
2 work and it's not going to hurt people. They failed.

3 I mentioned earlier that Boston Scientific made a
4 number of different products for women. And they did. One
5 such product was a Pinnacle product. And it's used to treat a
6 woman's issues as well. It's also transvaginally inserted.
7 Just like the Obtryx sling, it didn't have any human testing
8 done before it was made available for sale.

9 MR. ADAMS: Objection, Your Honor, with respect to
10 the Pinnacle.

11 THE COURT: Counsel, come to the bench here briefly,
12 please.

13 (The following occurred at sidebar.)

14 THE COURT: If I remember correctly, Judge Goodwin
15 has not made a ruling on the admissibility of the Pinnacle.
16 Am I correct about that?

17 MR. ADAMS: That is correct. Pinnacle is a POP
18 product, pelvic organ prolapse. This case is about SUI
19 products. He's referred to a number of SUI products and I
20 haven't objected. That's appropriate. Like he's referred to
21 the TVT which is a Johnson & Johnson product. And -- but
22 pelvic organ prolapse is a different product. So is the
23 Pinnacle.

24 MR. LOVE: If I could, both of these products have
25 the polypropylene mesh. And the reason why it's relevant and

Opening Statement - Mr. Love

1 I'll be able to establish and the evidence will show is that
2 neither one of these products had testing. But this
3 product -- actually, Boston made a decision to actually warn
4 physicians that they had no testing. So, they knew how to
5 warn. They just chose not to.

6 THE COURT: At this juncture, tell me if I'm correct
7 or not in my memory as to the status of the Judge's rulings
8 with regard to the admissibility of the Pinnacle.

9 MR. LOVE: He has not ruled.

10 THE COURT: Then I have ruled that that should not
11 come in in opening statements. I sustain the objection,
12 preserving the plaintiffs' objection and exception.

13 MR. ADAMS: Your Honor, would you inform the jury
14 that the objection is sustained so they know to disregard it?

15 THE COURT: Yes, sir.

16 MR. LOVE: And this --

17 Rob, just real quick.

18 This doesn't preclude our ability to lay a foundation
19 during trial and establish it.

20 THE COURT: No. My understanding, Mr. Love, from my
21 review of those motions is that that issue is outstanding
22 because the Judge wanted to see the context in which it came
23 in. I understand what you're proposing. But since it hasn't
24 been ruled on at this juncture, I'm going to preclude it in
25 opening as I stated on Friday.

Opening Statement - Mr. Love

1 MR. LOVE: Thank you, Your Honor.

2 (Sidebar concluded.)

3 THE COURT: Ladies and gentlemen of the jury, I have
4 sustained the objection as to the Pinnacle and, therefore, you
5 are to disregard any argument in reference to that.

6 MR. LOVE: May I proceed, Your Honor?

7 THE COURT: Yes, sir.

8 MR. LOVE: Okay. And what you're going to see over
9 the course of this trial is you're going to see this
10 Directions for Use quite a bit. And that's the Obtryx
11 Directions for Use and this is it. And this is the book that
12 contains the information that allows doctors to use their
13 products safely.

14 And as the evidence will establish, Boston Scientific
15 was told not to use this product for permanent implantation in
16 humans. And it will establish that they never did any testing
17 to establish that the product was safe and effective.

18 Unfortunately for my clients and the physicians who
19 performed these surgeries, none of this information was
20 included in this Directions for Use. And had the information
21 been included, the warning would have looked something like
22 this, and the warning would have told the doctor this
23 information:

24 "The safety and effectiveness of the Obtryx sling
25 compared to conventional surgical repair for stress urinary

Opening Statement - Mr. Love

1 incontinence has not been demonstrated in randomized
2 controlled trials," because that's the truth.

3 "We've been told by Chevron Phillips not to use this
4 for permanent implantation in humans." It's the truth.

5 Then the surgeons involved in this case could have
6 sat down with each one of my clients and had that discussion
7 and made an informed choice. And if they chose to go forward
8 knowing this, great. They would have made an informed
9 decision and we wouldn't be here.

10 Remember the Ross study that you're going to hear
11 about. You're going to also hear about a study called the
12 Cholhan study. After the Ross study was published, Boston
13 Scientific chose not to put this information in the Directions
14 for Use. If they would have, something like this should have
15 gone in: "That based upon human clinical trials recently
16 completed by Boston Scientific, we recommend physicians
17 continue to use the TVT as the mid-urethral sling of choice."

18 You remember Dr. Ross. That's the conclusion she
19 came to. Their paid consultant, that's her conclusion.
20 Doctors aren't made aware.

21 Now, you may see Boston Scientific show you this, so
22 I wanted to point it out for you. This is also in the
23 Directions for Use and it's call the potential complications
24 section. And what this does is it lists potential
25 complications that can occur.

Opening Statement - Mr. Love

1 And what Boston may argue is, "Hey, look at all the
2 stuff we did warn about. We warned about inflammation, pain,
3 infection, erosion, foreign body response, vaginal discharge.
4 We gave the doctors a lot of information. Isn't that good
5 enough?"

6 And the answer is absolutely not. You know why?
7 This information isn't based upon studies done on the Obtryx
8 sling. This information is based upon studies done on other
9 products. This is actually more misleading than putting
10 nothing at all.

11 MR. ADAMS: Objection, Your Honor. This is argument
12 again.

13 THE COURT: The objection as to it being misleading,
14 or more misleading, counsel, that phrasing I'm going to
15 sustain the objection.

16 MR. LOVE: Sure. Fair enough. Thank you, Your
17 Honor.

18 What you will learn through the evidence is that
19 there were no human studies done on the Obtryx sling. And,
20 so, they couldn't have put any warning in. If they were being
21 truthful and if they were being accurate in the information
22 that they were putting in, they would have said something like
23 this: "Boston Scientific does not know what complications are
24 associated with the Obtryx sling as it has never been tested
25 in humans. However, different products made by other

Opening Statement - Mr. Love

1 manufacturers to treat stress urinary incontinence have
2 reported the following complications in humans."

3 So, at least at that point the surgeons and my
4 clients could have sat down and said, "Listen, we're not sure
5 what problems are associated with this particular product, but
6 here's what other products made by other manufacturers have
7 reported."

8 The second question you're going to have to answer
9 is: Was the Obtryx sling defective? You heard the Judge.
10 That's one of our claims. Was it safe to use in humans?

11 And rather than going through all the evidence again,
12 you're going to see that they were told not to use it in
13 humans, that they made changes to the product that made it
14 different from any other product and never tested it.

15 You're going to hear about the Ross study. What
16 you'll also hear, the evidence will establish, that if the
17 Ross study is 2009, the Cholhan study is 2010, both of these
18 studies are Boston Scientific. They're the first and second
19 studies this company did.

20 And what you're going to hear is that had they done
21 these studies initially, we wouldn't be here because one of
22 the studies says, "Use a different product." The other study
23 says there may be as high as a 24 percent rate of pain during
24 sex, dyspareunia. If they had done the research they were
25 supposed to, they would have determined that the product was

Opening Statement - Mr. Love

1 defective from the get-go.

2 The last question you're going to have to answer:
3 How have the plaintiffs suffered in this case?

4 And you're going to get to meet Ms. Tyree, Ms.
5 Wilson, Ms. Campbell and Ms. Blankenship. You're going to get
6 to learn the stories and their stories and what they've been
7 through over the course of the last several years. And you're
8 going to meet each of them.

9 And you're going to find out that each of them are
10 from different walks of life, different backgrounds, different
11 socioeconomic classes, different political beliefs. But they
12 have a few things in common. They're your neighbors. They're
13 from West Virginia. They all have this product implanted in
14 them, or did have it implanted in them.

15 And there's one more thing they have in common.
16 They're all human beings and they deserve to be treated with
17 dignity and fairness. They all deserve to be told the truth.

18 And Boston took that away from them. Boston took
19 away their right to choose a different product, to seek a
20 different path because they didn't tell them the whole truth;
21 to choose a product that had actually been tested in humans.

22 They have one last thing in common. Every one of my
23 clients has had this product removed or revised in surgery
24 because of the problems this product has caused and the
25 problems it will cause for the rest of their lives, all four.

Opening Statement - Mr. Love

1 Now, Boston is never going to acknowledge that
2 they're responsible. They're not going to step up to the
3 plate and say, you know, "We're responsible for --"

4 MR. ADAMS: Objection, Your Honor. Again, this is
5 argument. This is not a discussion of evidence.

6 THE COURT: Mr. Love, any response to that objection?

7 MR. LOVE: Thank you, Your Honor.

8 THE COURT: Any response to that objection?

9 MR. LOVE: Oh, I was laying out what the evidence was
10 going to show. I don't believe that the evidence will show
11 that this company is going to take responsibility for their
12 conduct.

13 THE COURT: I think that is appropriate wording for
14 opening statement, counsel.

15 MR. LOVE: Thank you, Your Honor.

16 I don't think they're going to take responsibility
17 for their conduct. I don't think the evidence will show that
18 they are. They'll give you reasons why. They may blame the
19 surgeons. They may blame my clients. They may blame
20 everyone. But they're not going to look at themselves in the
21 mirror just like they're going to say, "Well, we warned about
22 a lot of stuff, but you're right. Maybe we didn't warn about
23 everything."

24 All four have had this product removed or revised.

25 My clients' journey. You're going to hear about

Opening Statement - Mr. Love

1 their journey from the time they had it implanted through
2 their first, second, or third surgeries. Each of these women
3 are at a different stage of a painful journey. And this isn't
4 one of those fun journeys. It's not a vacation by any means.
5 It's a journey filled with uncertainty, with pain, with future
6 medical care, a journey that none of these women deserve.

7 Ms. Blankenship you're going to hear had her Obtryx
8 removed, or at least a part of it. And she's had a third
9 surgery. Now her problem is actually fixed and she's doing
10 better, not great.

11 Ms. Tyree, on the other hand, had the Obtryx removed.
12 And you're going to hear that, as you might suspect, she's
13 scared about having anymore surgeries.

14 All different, all the same product, all on a
15 journey, just at different stages. But this is what they get
16 to look forward to the rest of their lives. All of these
17 women have experienced pain, intimacy issues with the ones
18 they love most, medical care, reoccurrence of their stress
19 urinary incontinence. And the tragedy is it all could have
20 been avoided if this company would have simply done its job.

21 Now, I'm not here and my colleagues aren't here and
22 my clients are not here today to tell you that every problem
23 they have is because of this sling. I'm not going to suggest
24 it. We're not going to say it because it's not the truth.
25 But just because they had some problems before their surgery

—Opening Statement - Mr. Adams—

1 doesn't give this company the right to make some of them worse
2 and create new ones.

3 This is a big case with big damages and very bad, big
4 decisions made by this company. Now, we've worked real hard
5 over the last four or five months to put this case together as
6 efficiently as we can, and we're going to bring you the
7 evidence so you can complete your investigation. We're not
8 going to waste your time.

9 On behalf of myself and my clients and my colleagues
10 here, I appreciate your time this morning. We look forward to
11 working with you over the course of the next couple weeks.
12 Thank you.

13 THE COURT: Counsel, Mr. Adams.

14 MR. ADAMS: Thank you, Your Honor.

15 May it please the Court, Your Honor.

16 THE COURT: Yes, sir.

17 MR. ADAMS: Ladies and gentlemen, this is a real-life
18 story about women seeking options for a life-altering
19 condition of stress urinary incontinence.

20 We all face conditions in our lives. And when
21 they're serious conditions or life-altering conditions, we go
22 to our doctors, and we talk with our doctors and our doctors
23 counsel us. And we have a choice to make. You can live with
24 the condition or you can do something about it. And the
25 doctors, when they tell you you can do something about it,

—Opening Statement - Mr. Adams—

1 they describe the risks. And here the only option available
2 for these ladies was a surgical option.

3 Now, you've just heard a very nice discussion from
4 Mr. Love. But one thing that was absent, starkly absent was
5 any discussion about the treating physicians, what they knew,
6 what these women's conditions were, and why they chose the
7 Obtryx. This case is really a story about women seeking
8 options for a life-altering condition.

9 Now, the women in this case, there are four of them.
10 And, actually, two of the women went to the same treating
11 doctor. That's Dr. Bhanot. So, there's really only three
12 doctors that we're talking about in this case. There's Dr.
13 Bhanot, Dr. Lassere, and Dr. Luby.

14 And the central question that you have to decide is
15 why is it that all three of these doctors located nearby,
16 right here in West Virginia, all three of these doctors who
17 care about their patients, who read up on the medical
18 literature, who stay current and who have been in the practice
19 of medicine for a combined number of 71 years, why did they
20 all choose this product? That's the central issue in this
21 case.

22 And, ladies and gentlemen, they all chose the Obtryx
23 because their experience, their clinical experience in
24 treating other women showed to them that this product is safe
25 and it's effective. If it wasn't safe and effective, based

—Opening Statement - Mr. Adams—

1 upon their treatment of other women, they wouldn't have
2 recommended it to these women.

3 Again, these doctors -- Dr. Bhanot you didn't hear
4 anything about in the opening statement of the plaintiffs, 28
5 years of clinical experience.

6 Dr. Lassere, 22 years of clinical experience.

7 Dr. Luby, 23 years of clinical experience.

8 They chose the Obtryx based upon the medical
9 literature that they routinely review, and they chose the
10 Obtryx based upon their clinical experience.

11 Now, what does clinical experience mean? Clinical
12 experience means that these doctors had used these products
13 well in advance of the time that they used them with the
14 plaintiffs at issue and they had good results.

15 Boston Scientific sells products to hospitals, and
16 doctors can choose or not to choose -- not, not use the
17 products. At any time if these doctors felt that that product
18 was unsafe, if they were getting bad results with any of the
19 other patients that they treated, they could simply go to
20 another product. But they didn't do that. They chose the
21 Obtryx.

22 Let's focus on Dr. Bhanot. Dr. Bhanot, you're going
23 to hear his -- you may hear his deposition or he may come here
24 live. And a deposition is just like live testimony. Here's
25 what Dr. Bhanot knew about the Obtryx and his prior knowledge.

Opening Statement - Mr. Adams

1 He went to medical school in 19 -- graduated in 1972.
2 He's a board certified urologist. He, like other doctors,
3 engage in continuing legal education -- not legal education,
4 medical education about products. They also belong to
5 professional organizations. You're going to hear about
6 professional organizations of doctors like these doctors at
7 issue.

8 And all of these doctors are not internists. They're
9 specialty doctors who treat the condition of stress urinary
10 incontinence. That is the majority of their practice. And
11 Dr. Bhanot kept up on the medical literature. He goes to
12 medical conferences. And he had personal experience with not
13 only the Obtryx, but other types of what are called
14 mid-urethral slings.

15 And the Obtryx is not the only product out there.
16 So, when Mr. Love was talking about the Obtryx and showing
17 these devices, there's a long history that I'm going to tell
18 you about of other devices that have been used in women since
19 the 1990s.

20 Dr. Bhanot also went to various training programs to
21 learn from different companies and different experts about how
22 to safely use these product.

23 Let's talk about his clinical experience. He
24 performed nearly 700 -- has performed nearly 700 mid-urethral
25 surgeries. And most of those surgeries involve the Obtryx.

—Opening Statement - Mr. Adams—

1 At least 90 percent of his patients substantially improved
2 after the surgery. And he's had a very low complication rate.

3 It goes back to what I told you, talked about
4 earlier, that when we go to our doctors and our doctors give
5 us options, we have to weigh the risks of engaging in an
6 option like surgery versus the benefit of having that
7 condition resolved.

8 That's the issue that all of these women and all of
9 the doctors had to judge and had to go through. You weigh the
10 risks of the surgery versus the benefit of having the
11 condition eliminated or resolved.

12 And based on Dr. Bhanot's experience, at least
13 90 percent of his patients substantially improved after the
14 surgery. And he will tell you that he had a very low
15 complication rate. Again, if he didn't believe that this
16 product was effective, he would not have recommended it to two
17 of the women in this case.

18 Let's talk about his experience with other SUI
19 treatments. Now, we've been talking about stress urinary
20 incontinence. And there's really going to be no dispute in
21 this case that all four of these ladies, all four of these
22 ladies have severe stress urinary incontinence.

23 Mr. Love talked about other options that were
24 available like exercises. They're called Kegel exercises. He
25 mentioned some other different types of therapies. But for

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1 these women, their SUI was severe enough that those were not
2 options. Really, the only thing that was going to resolve
3 their condition -- and you'll hear this from the doctors. The
4 only thing that was going to resolve this condition was
5 surgery.

6 And, in fact, Dr. Bhanot will tell you that the Kegel
7 exercises rarely work. There's also some devices that are
8 actually bulking agents which can be injected. And they're
9 ineffective.

10 And then there's some other surgical procedures.
11 There's a procedure that you're going to hear about called the
12 MMK. That's where an incision is made in the abdomen.
13 There's a procedure called the Burch procedure. And that also
14 has a lot of complications associated with it according to Dr.
15 Bhanot.

16 And Dr. Bhanot will tell you that the success rate of
17 mid-urethral slings is superior to the other procedures.
18 These doctors don't just practice in a vacuum. So, when
19 Mr. Love was talking about Boston Scientific did this and
20 Boston Scientific did that, we didn't tell them about a study,
21 I want you to keep in mind the studies that he talked about,
22 Ross and Cholhan, are published in the literature. Doctors
23 read the literature. Boston Scientific isn't withholding
24 studies. They're actually published so doctors can read it.

25 Let's talk about Dr. Lassere's knowledge. Dr.

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1 Lassere went to medical school, board certified. He does the
2 same type of continuing education. He keeps up on the medical
3 literature. He goes to medical conferences. And he had
4 personal experience with mesh and he went to different
5 training programs.

6 His experience with the Obtryx -- he actually started
7 using mid-urethral slings back in the late 1990s. I'm going
8 to talk more about the history. But, again, Boston Scientific
9 didn't come up with the idea of using polypropylene mesh to
10 treat women with stress urinary incontinence.

11 You're actually going to find out that it was
12 surgeons who took the concept of using polypropylene mesh that
13 was actually originally used in hernia surgeries. They took
14 that concept and they cut strips of mesh in order to place it
15 underneath the urethra.

16 So, medical device companies, and certainly not
17 Boston Scientific, didn't come up with the idea. It was the
18 surgeons who came up with the idea.

19 So, back in the 1990s Dr. Lassere first started using
20 mid-urethral slings. And he changed to the Obtryx in about
21 2007, 2008. He's performed approximately 50 Obtryx surgeries,
22 probably more by now. And he's had a positive clinical
23 experience with the Obtryx.

24 And the erosion rate -- and erosion, we'll talk about
25 that later, but that's one of the complications that you're

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1 going to hear about in this case. His erosion rate for all of
2 his patients is one percent or less.

3 So, why does he use the Obtryx and mid-urethral
4 slings over the other options that I talked to you about? He
5 will tell you that the mid-urethral sling is superior to the
6 Burch procedure.

7 Now, I've been using the term "mid-urethral sling."
8 The Obtryx is a mid-urethral sling. The plaintiffs will not
9 dispute that. You're going to find out that the
10 classification of mid-urethral slings, they basically all
11 involve the similar concept of using a thin strip, thin light
12 strip of polypropylene mesh to place it transvaginally
13 underneath the urethra to provide a hammock. And that
14 hammock -- basically, when a woman coughs or sneezes, it
15 prevents the leakage of urine.

16 Let's talk about Dr. Luby's knowledge. Again, all of
17 these gentlemen are local practitioners. Dr. Luby, medical
18 school in 1990, board certified OB/GYN. He's done continuing
19 legal education. He's a member of all the major organizations
20 that you're going to hear about. He keeps up on the medical
21 literature and he goes to conferences. And he talks with
22 other doctors. That's another important thing.

23 Again, these doctors don't just practice in a vacuum.
24 They go to meetings where they talk with other doctors. They
25 go to ground, grand rounds which are actually meetings within

—Opening Statement - Mr. Adams—

1 their hospital where they talk with other people that practice
2 in their area about devices, surgical options, and what people
3 are using.

4 Dr. Luby used the Obtryx and he's performed
5 approximately 200 Obtryx surgeries. He says that
6 mid-urethral, mid-urethral slings like the Obtryx are the gold
7 standard for the treatment of stress urinary incontinence.
8 He's had a 95 to 99 percent success rate.

9 His complications -- he's really had no complaints.
10 And Ms. Tyree was one of his few patients who had complaints
11 about dyspareunia.

12 Dr. Luby had similar experience with the other older
13 treatments; said that Kegel exercises are rarely effective.
14 The Burch procedure is more invasive. And we'll talk a little
15 bit about that. I've already referenced the fact that the
16 Burch procedure and what's called the MMK procedure involve a
17 cut in the abdomen. Women have to spend one to two days in
18 the hospital. And their recovery time is much longer.

19 There's also things such as a native tissue repair.
20 He says that in his practice that is reserved as a last resort
21 for patients. And then, again, I mentioned bulking agents.
22 He said bulking agents are less effective than mid-urethral
23 slings. So, I want you to think about the clinical experience
24 of these doctors.

25 Now, Mr. Love referred to two different articles and

Opening Statement - Mr. Adams

1 I'll talk about those later. But let's just consider the
2 experience of these doctors as if it was an article in and of
3 itself.

4 Their experience, if you combine it all together,
5 they've placed approximately 550 Obtryx slings and they've had
6 very low complication rates, 90 percent success, 95 percent
7 success. And all of them believe that the mid-urethral sling
8 like the Obtryx are the gold standard or the standard of care
9 to treat SUI or stress urinary incontinence.

10 Again, these doctors are on the ground, boots on the
11 ground practicing every day doing these procedures. And they
12 see whether their patients experience any type of
13 complications.

14 At any point in time if they had problems with the
15 Obtryx, they would have done what they should do for their
16 patients and used another product. But they didn't. They
17 continued to use the product and they've done what other
18 doctors do out in practicing medicine.

19 And it goes back to what I said right from the start.
20 When you have an option presented to you about how to get rid
21 of a life-altering condition, it involves a balancing of the
22 risks of a procedure like a Burch procedure or an MMK or using
23 a mid-urethral sling. What are the risks versus the benefits.

24 The benefits are that the conditions, problems can be
25 eliminated or substantially reduced. And that's what doctors

Opening Statement - Mr. Adams

1 do every single day when they recommend procedures, products,
2 drugs to us when we have conditions.

3 You know what. Everything has risks. If we take --
4 if we have some type of condition and we take a drug, that
5 drug, if you open up the pill bottle or get it from your
6 pharmacy, it's got risks associated with it. If you undergo
7 any type of surgery, it has risks associated with it. It
8 involves a trade-off.

9 And the trade-off that patients like these women and
10 us when we have different types of operations, the trade-offs
11 are: Are the risks outweighed by the benefits, or do the
12 benefits greatly exceed the risks?

13 And for these doctors that we've talked about, you're
14 not going to hear from their other patients. You're just
15 hearing from four people. But think about it. 550 women at
16 least were treated by these doctors. 90 to 95 percent of
17 these women had successful outcomes. You won't hear from
18 them.

19 So, Mr. Love is right. This case is going to come
20 down to really three questions. And I liked his, his
21 reference to the *CSI* and the *Cold Case* because you know what.
22 This case is about when you're examining the evidence, you're
23 looking at it without passion, without prejudice. And you're
24 looking at it in a scientific way. You're looking at, well,
25 what makes sense?

—Opening Statement - Mr. Adams—

1 And one thing that's going to be important is -- and
2 you've already saw it. Mr. Love showed a picture of Boston,
3 the city of Boston. He talked about Boston Scientific. Well,
4 Boston Scientific is actually located about 45 miles outside
5 of Boston. And given the traffic, it takes about an hour and
6 a half. It's like being located in Huntington. And it's
7 located in a small, somewhat, almost a rural area. It's
8 outside of a little town called Marlborough.

9 And when you're examining the evidence, you need to
10 keep in mind that Boston Scientific is composed of people.
11 And those people under the law are entitled to the same
12 consideration as the four nice ladies who Mr. Love represents.
13 So, you shouldn't let passion or prejudice or any bad feelings
14 about a corporation enter into this process. That's not what
15 it's about.

16 It's about looking at the evidence scientifically.
17 And you're going to look at three questions. Is the Obtryx
18 safe and effective? Has Boston Scientific adequately warned
19 doctors about the product? And are the injuries that the
20 plaintiffs have caused by a defect in the Obtryx?

21 So, let me give you a road map of what I'm going to
22 talk about for the remainder of our discussion.

23 First, we're going to talk a little bit about the
24 disease of stress urinary incontinence. Then I'm going to
25 talk about the treatments associated with that. And we've

—Opening Statement - Mr. Adams—

1 already talked a little bit about it. And then I'm going to
2 talk about the Obtryx and the plaintiffs.

3 So, let's begin. Now, Mr. Love has talked to you
4 basically about stress urinary incontinence, but I want you to
5 understand exactly how it works.

6 Here is the normal female anatomy. And you can see
7 the urethra. And most of our discussion is going to be
8 focused on the urethra. And Mr. Love is right. Due to age,
9 gravity, and just the natural processes of our bodies when we
10 get older, especially women who have children, they develop a
11 loosening of the pelvic floor that allows the urethra to get
12 in the position to where it can leak urine.

13 And there's no dispute in this case that stress,
14 severe stress urinary incontinence is a life-altering
15 condition. You're going to hear about the horrible issues
16 that these women had to deal with. And no woman should have
17 to deal with that.

18 Stress urinary incontinence occurs when pressure
19 either from coughing, sneezing, lifting, and doing other
20 things, when pressure is placed inside the body, it moves to
21 the bladder and then it causes the urine to leak out of the
22 bladder.

23 And that pressure, at times it can get severe enough,
24 and you're going to hear from the plaintiffs, that it can
25 become severe enough that women are forced to wear adult

—Opening Statement - Mr. Adams—

1 diapers. They have to change their clothes several times a
2 day.

3 One of the ladies in the case talked about how she
4 had to change her clothes four times a day. Women shouldn't
5 have to live that way. And, in fact, stress urinary
6 incontinence affects many women. There's estimates and
7 there's scientific literature that 50 percent of women as they
8 get older, especially women who have babies, they're going to
9 have stress urinary incontinence.

10 And 30 percent of those women are going to need
11 surgery. They're going to need surgery because it's severe
12 stress urinary incontinence. It goes back to the options.
13 Other options that are not surgical options weren't available
14 to these ladies. And their doctors knew that. Otherwise,
15 they would have chose some other treatment. But they chose
16 the surgical option.

17 So, when you look at the options, there's nonsurgical
18 and surgical. These ladies had to have a surgical option.
19 When you get into the field of surgical options, you're going
20 to hear about traditional procedures. And these procedures
21 have been around a long time. There's a Burch procedure.
22 There's another one called the MMK. And sometimes they refer
23 to it as traditional or older procedures.

24 And then you're going to hear about mid-urethral
25 slings. And, again, doctors came up with the idea of

—Opening Statement - Mr. Adams—

1 mid-urethral slings. And it's really -- the story is
2 fascinating. The story goes back to the 1950s when mesh first
3 started to be used in hernias. And doctors talk -- surgeons
4 talk about the efficacy of different products.

5 So, at some time after surgeons started using
6 polypropylene mesh to treat hernias, later you're going to
7 hear that in the '60s and the '70s doctors were custom cutting
8 pieces of that same polypropylene mesh and using it to treat
9 stress urinary incontinence. And, again, the Obtryx is a type
10 of mid-urethral sling.

11 These are a list of the other older procedures,
12 procedures that have been around for a long time. And then we
13 have the mid-urethral sling which really started in the '70s,
14 but manufacturers started making those products because
15 surgeons were custom cutting it. There was a need for
16 companies to make the products.

17 And you'll hear that the first company to do that was
18 actually Johnson & Johnson, or a division of Johnson & Johnson
19 in the 1990s.

20 The Burch procedure is an abdominal procedure. It
21 involves a cut in a woman's stomach.

22 The MMK is abdominal. You're going to hear that
23 there's other procedures that are abdominal surgeries.

24 There's actually an interesting surgery that's the
25 use of a pubovaginal sling. That's where, again, you're

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1 making an abdominal incision and you're actually taking cuts
2 of a woman's skin or tissue and using that same tissue to
3 create a sling. All of these procedures were rejected by the
4 three doctors who treated these ladies.

5 Now, I want to talk about Ms. Campbell's SUI. And
6 I'm not going to, not going to belabor this point. I don't
7 think that even the plaintiffs are going to contest the fact
8 that they all needed the surgical option. She talked about
9 how she was asked questions. And we were entitled to take the
10 depositions of these ladies before and find out about their
11 condition.

12 And she talked about her condition. And we asked
13 her, "On a scale of one to ten, how has this affected your
14 quality of life?" She said, "At least a ten." And then I
15 already discussed with you the other issues about basically
16 she said she was leaking all over herself, having to change
17 her clothes four to five times a day, missing social events.

18 Ms. Wilson also had severe SUI. She was spraying
19 urine at the end of 2009 when she coughed, sneezed, lifted
20 items, when she had sex.

21 And, again, ladies and gentlemen, when we discuss --
22 when Mr. Love and I discuss these issues, I want to make one
23 thing perfectly clear. I agree with him that these are nice
24 ladies. These are nice ladies. And we need to be respectful
25 to their issues. And when we talk about the conditions, in no

—Opening Statement - Mr. Adams—

1 way do either Mr. Love nor I mean any disrespect. But,
2 frankly, that's what this case is about.

3 If this case was about the issue of whether they're
4 nice people or whether you may have sympathy for them, you
5 know what? There would be no reason for a trial. But it's
6 not about that. It's about a search based upon the evidence
7 to answer those three questions that I talked about earlier.

8 So, even though you may feel sympathetic to them, you
9 need to set that aside. You know, there's a great quote from
10 Oliver Wendell Holmes that -- he was one of the Supreme Court
11 Justices. And he said sympathy is one of mankind's greatest
12 human virtues, but it has no place in the courtroom.

13 So, when you look at this evidence, you need to judge
14 it based upon the facts. And it's unquestionable that all of
15 these women had severe SUI. Ms. Blankenship had to wear pads.
16 Eventually she had to wear adult diapers. She had irritation
17 from wet pads.

18 Ms. Tyree, again, severe SUI. She went to Dr. Luby
19 because she didn't want to suffer anymore from the stress
20 urinary incontinence problems.

21 Now, I want to talk to you about the Obtryx. As I
22 said before, the Obtryx is a class of device called a
23 mid-urethral sling. Boston Scientific didn't invent that
24 device. Other companies invented the idea for the device. And
25 I think you may have had the impression that somehow Boston

—Opening Statement - Mr. Adams—

1 Scientific had created just this device and it sold it to
2 these physicians and somehow duped them into using it. Well,
3 that's not true. This device has been around -- the type of
4 device has been around for a long time.

5 And you're going to hear about studies about how many
6 different doctors, like the three doctors that I showed you
7 before, how many different doctors use the same types of
8 devices that involve polypropylene mesh placed transvaginally
9 inside the vagina to anchor the urethra.

10 Here's a study -- and you're going to hear a lot
11 about studies. Here's a study that is actually out of a
12 journal, the *Female Urology Journal*, and it's entitled
13 "Mid-Urethral Sling is the Dominant Procedure for Female
14 Stress Urinary Incontinence."

15 And what the study did is it looked at doctors who
16 were board certified. And it said they looked at a total of
17 6,355 urologists. And the conclusion of the study after they
18 looked at and researched what these doctors were using to
19 treat this condition, here's their conclusion."

20 "Mid-urethral slings have been widely adopted by
21 urologists over the last decade. Increase in sling usage
22 coincided with a drastic decline in traditional procedures,
23 implying that the newer mid-urethral slings were replacing
24 these traditional procedures for the treatment of female
25 urinary incontinence."

—Opening Statement - Mr. Adams—

1 And, ladies and gentlemen, that's what all these
2 three treating physicians said. They don't do these other
3 procedures. They use devices that are very similar to the
4 Obtryx.

5 Here's also what the article said. It said, "The
6 large increase in the use of sling procedures over the past
7 decade, combined with the relatively stable number of
8 periurethral injections, indicates that traditional
9 repairs --" those are the repairs with the cuts to the
10 abdomen. Sometimes you can do it laparoscopically.
11 "Traditional repairs have almost entirely been replaced by
12 mid-urethral sling procedures. Between 2003 and 2012, the
13 number of traditional procedures fell from 784, or 17 percent,
14 to just 56. One percent of the treating physicians do those
15 repairs."

16 And this chart stands for that proposition. You can
17 see at the top these are the traditional repairs that have
18 decreased down to about one percent of the doctors.

19 So, these three doctors that we've been talking about
20 that you didn't hear much about in opening statement, those
21 three doctors, like the majority of doctors out in the world
22 practicing in their specialty, offer the same type of device
23 to their patients. And the Obtryx sling you're going to hear
24 about is a device that is like all the other mid-urethral
25 slings.

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1 Now, there are two different types of approaches that
2 are going to come up in this case. And I'm going to explain
3 that to you in a minute.

4 The Obtryx is placed -- and you saw the trocars.

5 Mr. Love, do you have the trocar?

6 MR. LOVE: I do.

7 MR. ADAMS: Thank you. May I use that?

8 MR. LOVE: You may.

9 MR. ADAMS: Thank you.

10 The Obtryx sling is placed in a woman's body by the
11 use of a trocar. And, ladies and gentlemen, frankly, you know
12 what? When I looked at this -- when I looked at this for the
13 first time, I was concerned about it. You know that? I'm not
14 a surgeon and I looked at it and thought, wow, I've never seen
15 a device like that. But these types of devices are common in
16 surgery, and these doctors use these devices every single day.

17 And this is the piece of mesh -- and I want you to
18 understand that this piece, this entire piece does not stay
19 within a woman's body. The piece is trimmed off after it's
20 placed in the body. It's placed in the body by making a cut
21 underneath the urethra. And then the Obtryx -- those devices
22 called the trocars go through. And this is called the
23 obturator foramen. This is the pelvic. So, it goes through
24 the obturator foramen on one side or the other and it's placed
25 underneath the urethra.

—Opening Statement - Mr. Adams—

1 And you're going to see that all of the mid-urethral
2 slings involve the same type of procedure. There are some
3 different techniques and there's also different placements
4 that you're going to hear about. But that's basically how the
5 device works.

6 So, here's a diagram showing you how the sling is
7 placed. You can see that this is the pubic bone. And the
8 sling is placed so that it actually provides a support or a
9 hammock. I used that term before. It's a hammock to
10 generally go underneath the urethra so if a woman coughs or
11 sneezes or does other things, she doesn't leak urine.

12 We talked about the history of polypropylene mesh.
13 And I told you about that really back before even this
14 timeline, surgeons came up with the idea of taking
15 polypropylene mesh that has been used in surgeries since the
16 1950s for hernia repairs. Smart doctors came up with a
17 concept of cutting sheets of mesh into thin strips like this
18 and then placing that transvaginally through the woman's
19 vagina.

20 And then what happened is that medical device
21 companies in working with physicians recognized that there was
22 a need for devices that were already pre-cut and pre-made.

23 And the first company to come out with the first
24 mid-urethral sling was Johnson & Johnson with the TVT in 1997.
25 And the TVT involved the same type of mesh, polypropylene

—Opening Statement - Mr. Adams—

1 mesh, but it was placed in a little bit different position and
2 they had a different approach.

3 Then you'll see that there was another sling that
4 came out from another company. And then you'll see that
5 Boston Scientific came out with their first sling which was
6 called the Boston Scientific Advantage sling in 2002.

7 So, again, you can see that five years before the TVT
8 was already out on the marketplace, five years later Boston
9 Scientific came out with their sling. And that's important
10 because, again, Boston Scientific was able to observe the
11 studies and the reports of the success of the TVT in the
12 marketplace and the fact that there were very low
13 complications and it was an effective surgery and Boston
14 Scientific then came out with the Advantage and the Lynx.

15 Now, I've talked about the different approaches.
16 These approaches -- the first three products that are on here
17 involved the retropubic approach. The other approaches are
18 transobturator approaches. You can see there was a MonArc
19 sling, a TVT-O, and the Boston Scientific Obtryx.

20 Now, I'll explain what that means in a moment. But I
21 wanted you to know that at the start all of these products use
22 the same type of polypropylene mesh. But the first three
23 products, including Boston Scientific's Advantage, was a
24 retropubic approach. The next three products are what's call
25 the transobturator approach.

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1 Now, why did the transobturator approach come about?
2 You're going to hear that there was a reduced incidence of
3 bladder injuries in the procedure. And that's why there was
4 another option advanced or put out in the marketplace called
5 the transobturator approach.

6 Both of these options still remain available to
7 surgeons. And surgeons are the ones who ultimately make the
8 call as to whether they like one product versus another.

9 So, let's talk about the development of the mesh.
10 Mr. Love talked about information that Boston Scientific knew
11 about this product. Well, what we knew about polypropylene
12 mesh was that polypropylene mesh had been around since the
13 1950s. We were able to -- the people at Boston Scientific
14 were able to observe the success of the TVT and the fact that
15 that was providing great benefit to women in the marketplace.

16 So, Boston Scientific when it created its first sling
17 actually had an engineer named Doreen Rao research the issue
18 on the mesh used by the TVT. And she went out and she did
19 research and you're going to hear about that. And the
20 original Advantage mesh which was first used in the Advantage
21 and then later used in the Obtryx, it's the same mesh.

22 What did Boston Scientific do and task Doreen Rao to
23 do? We tasked her to basically create the same type of mesh.
24 And here's a photograph showing the Advantage mesh which is
25 used in the Advantage product and the Obtryx product and the

—Opening Statement - Mr. Adams—

1 TVT mesh. They're almost identical. And it's the same type
2 of material, which is polypropylene. Again, polypropylene has
3 been used in the body since the 1950s.

4 So, when you hear Mr. Love talk about Boston
5 Scientific had these warning signs and Boston Scientific
6 should not have used polypropylene, keep in mind that we
7 fashioned our mesh, the Advantage mesh that, again, is used in
8 the Obtryx to be just like the TVT.

9 Now, I talked about the two different approaches.
10 Some products are retropubic. Those are the three products
11 that I mentioned before. The TVT was the first one. Other
12 products like the Obtryx are through the transobturator
13 approach.

14 Now, there's risks and benefits associated with each
15 product. It's like what I've said repeatedly. The
16 transobturator approach, the benefit of that is there's a
17 reduced incidence of perforation of the bladder in the
18 procedure. Other doctors prefer retropubic. The doctors at
19 issue here like the transobturator approach.

20 Here's a chart that shows -- and it's really going to
21 be undisputed in this case. Polypropylene has been used in
22 the body, different parts of the body for 55 years. It's not
23 just used in hernias. It's used in chest walls. It's used in
24 fingers. It's used in all sorts of different locations. And
25 that's going to be undisputed in this case. But in this case

—Opening Statement - Mr. Adams—

1 we're going to be focusing on the use of polypropylene
2 specifically underneath the urethra. And, again, there's even
3 incidents of the use of polypropylene in the head and the
4 brain.

5 Now, I want to focus on Boston Scientific's history
6 and use of the specific type of polypropylene at issue.

7 Now, Mr. Love spent a substantial amount of his
8 opening statement talking about Boston Scientific didn't
9 properly test the product, and Boston Scientific was told by
10 the supplier of the polypropylene to not use this product in
11 humans.

12 And you know what. I looked over and I saw that you
13 were concerned. And you know what. You should be. You
14 should be. And I'll tell you that Boston Scientific reacted
15 immediately when it received that information. But what's
16 interesting is the history about the information, about, "Do
17 not use this in human bodies."

18 Now, Mr. Love didn't show you the document. It
19 actually is a document that accompanied the polypropylene
20 resin. Now, polypropylene resin is the raw ingredient that is
21 actually spun into fibers and then woven into the mesh.

22 So, when he talks about this labeling that says "not
23 for human use," or something to that effect -- and you'll see
24 it later. It's called an MSDS sheet. What's important to
25 note is that Boston Scientific was buying that polypropylene

Opening Statement - Mr. Adams

1 mesh -- or buying the polypropylene pellets for use in its
2 products since 1992.

3 Since 1992 we were buying the same exact type of
4 polypropylene from a company called Phillips. It started with
5 the mesh called the Trelex mesh which was used for hernia
6 repairs. And then in 2002 we talked about the Boston
7 Scientific's Advantage sling that came out. We were using the
8 same type of polypropylene. And then in 2004 the Obtryx was
9 introduced. And then later in 2008 we've come out with
10 another sling.

11 What's important to note is that this same
12 polypropylene pellets that were spun in the mesh, into the
13 mesh has been used since 1992 in mesh placed inside the human
14 body. And biocompatibility testing was done by Boston
15 Scientific on this polypropylene. And it was established
16 through testing.

17 It's not only established through testing. It's
18 established through a history of use of polypropylene, the
19 same exact polypropylene in the body since 1992 in Boston
20 Scientific's products.

21 Now, this medical -- this MSDS that contained the
22 language that Mr. Love talked about, it was not contained
23 within any of the pellets or the raw material from 1992 all
24 the way until 2004. So, from 1992 to 2004 this statement in
25 what's call the MSDS sheet was never contained within the

Opening Statement - Mr. Adams

1 material that was received from Phillips Sumika to Boston
2 Scientific.

3 Now, in 2004 they added a statement saying, "Not for
4 use in the human body." And, again, Boston Scientific when it
5 got word of that statement was concerned about it and reacted
6 immediately.

7 And what did we find out? We found out that there
8 was no scientific basis and no studies -- nothing was done by
9 this company to support its claim in 2004, years after it
10 first started supplying us the same polypropylene pellets,
11 that there was no scientific basis for that statement.

12 And you're going to hear in this case -- in fact, a
13 gentleman from the company -- and we took the deposition of
14 the corporation and we asked them to provide a representative
15 who could talk on the issues as to whether there was a
16 scientific basis for the statement. And you're going to hear
17 the deposition of Mr. Frank Zakrzewski. He's going to say
18 that that statement was not added based on any scientific
19 testing. It was not added based upon any polypropylene data.
20 And it was not added based upon any scientific or medical
21 literature.

22 And, in fact, you're going to hear from Doreen Rao.
23 Doreen Rao is -- and plaintiffs are going to call her
24 tomorrow. She will tell you that after this change in the
25 MSDS was received, she actually was told by people at Phillips

—Opening Statement - Mr. Adams—

1 Sumika that the statement was put in for some type of legal
2 reason. It was not put in for any type of medical -- not
3 based on any type of medical or scientific basis.

4 Now, so, when you hear plaintiffs talk about this
5 MSDS language, you're just going to hear plaintiffs' portion
6 of the case. Keep in mind this will be a ten-day trial. And
7 plaintiffs get to choose bits and pieces of evidence that they
8 may show you in depositions that will be played to you or
9 through statements of witnesses. Keep in mind that you need
10 to have an open mind and wait for all of the evidence to come
11 in for Boston Scientific.

12 And, again, it's going to be undisputed in this case
13 that mid-urethral slings are really the gold standard for the
14 use of doctors, and that the Obtryx device is in the same
15 classification. And, again, it's the same basic principle
16 using the same material.

17 You're going to see a lot of literature. This
18 literature talks about the transobturator sling has become one
19 of the most popular and effective surgical treatments for
20 female stress urinary incontinence worldwide.

21 You're going to hear about position statements.
22 Remember when I showed you the history of those doctors before
23 and talked about the different societies that they belong to.
24 All of the major societies of doctors who treat women, you're
25 going to hear that they have come out with position statements

—Opening Statement - Mr. Adams—

1 that are supportive of the use of polypropylene slings.

2 Here's a position statement from a group called AUGS.
3 It says -- and AUGS is the American Urogynecological Society.
4 And it's down here in the fine print. And there's another
5 group called SUFU. You're going to hear about a bunch of
6 different groups that doctors like the three doctors that are
7 the main characters in our case belong to. And they care
8 about their patients and they study products.

9 Here's the position statement from AUGS. It says,
10 "The polypropylene mesh mid-urethral sling is the recognized
11 worldwide standard of care for the surgical treatment of
12 stress urinary incontinence. This procedure is safe,
13 effective, and has improved the quality of life for millions
14 of women."

15 Again, when you think about the doctors at issue,
16 those three doctors that I've said have done 50 Obtryx
17 procedures, they said that their success rate is 90 percent or
18 more. You won't hear from the 90 percent of those patients
19 who got a great benefit.

20 This group also talked about polypropylene material
21 and said it's safe and effective for use as a surgical
22 implant. Remember the diagram I showed you earlier. They say
23 that this material is used in cardiovascular surgery, eye
24 surgery, gynecology surgery. It's been used for more than
25 five decades.

—Opening Statement - Mr. Adams—

1 And then they say that, "As a knitted implant for the
2 surgical treatment of stress urinary incontinence,
3 macroporous, monofilament, lightweight polypropylene has
4 demonstrated long-term durability, safety, and efficacy up to
5 17 years."

6 They go on to say, "It's one of the most extensively
7 studied anti-incontinence procedures in history." And then
8 they talk about how it's the standard of care. And, again,
9 you'll hear the term "gold standard."

10 More than three million mid-urethral slings have been
11 placed worldwide. So, it's not just our three doctors located
12 in West Virginia here treating these nice ladies who use these
13 products. These products are used worldwide. And the Obtryx
14 is sold worldwide.

15 They say the procedure is probably the most important
16 advancement in the treatment of stress urinary incontinence in
17 the last 50 years. There's other organizations -- and I'm not
18 going to take the time -- that also support these same
19 devices. You're going to hear about studies. And the studies
20 all conclude that these devices are safe and they are
21 effective.

22 And really nobody in this courtroom and not the
23 plaintiffs are going to dispute that mid-urethral slings like
24 the Obtryx are the most studied procedure for incontinence.
25 It's the most used treatment and they're the most effective

—Opening Statement - Mr. Adams—

1 treatment and they're safe.

2 Now, so, what you heard Mr. Love talk about is,
3 "Well, there's something different about the Obtryx. There's
4 something different." Well, what's different about it?

5 He points to, again, this language that was within
6 the pellets, the raw material, the MSDS. It changed. It
7 changed because in 2004 for legal reasons they decided to put
8 that language in there. They didn't do any type of testing.
9 Boston Scientific had already done the testing. And they did
10 more testing. And they found basically what they knew before,
11 that polypropylene, and this specific polypropylene, was safe
12 and effective.

13 So, what's different? Well, Mr. Love has talked
14 about the Ross study and he talked about the Cholhan study.
15 I, I can assure you of this. By the end of this case, you
16 will be sick about hearing about studies. You know what? For
17 every study that is going to be brought up, you're going to
18 hear criticisms about the study.

19 The doctors, the three doctors at issue in this case,
20 they all read the studies. They see the different doctors
21 reach different conclusions. At the end of the day, that's
22 why they rely upon their clinical experience.

23 Now, Mr. Love talked about Boston Scientific withheld
24 these studies. You know what. That really doesn't make
25 sense. If we were trying to do that, we didn't do a very good

—Opening Statement - Mr. Adams—

1 job of it because these studies are published in the
2 scientific literature. The Ross study is published in a
3 urogynecology journal. It's available for doctors to read.
4 Same with the Cholhan study.

5 An important part about it is that the Ross study and
6 Cholhan, they do reach certain conclusions about the Obtryx.
7 And you know what. The doctors -- like I said before, studies
8 vary. But what you're going to find out in this case is that
9 the overall majority of these studies conclude that the Obtryx
10 device is safe and effective.

11 And, in fact, there's a recent study. It wasn't on
12 Mr. Love's chart, but there's a recent study that just came
13 out in 2014 by some doctors in Turkey that say that this
14 device is safe and effective.

15 I put parentheses around, next to the titles of these
16 different studies because you can see that the volume of
17 patients who were involved in the studies varies from study to
18 study.

19 And, again, there's going to be a great debate upon
20 these studies. But at the end of the day, I believe these
21 studies will show that the device is safe and effective.

22 This is the Tarcan study. That is the 2014 study
23 that just came out. It was published online and says, "The
24 aim of the study was to evaluate the safety and efficacy of
25 the retropubic or transobturator TO mid-urethral sling."

—Opening Statement - Mr. Adams—

1 Again, that's the Advantage, which is one of our
2 products, was compared to the Obtryx. And the conclusion
3 reached was that both devices are highly effective. And there
4 is no significant difference between the retropubic approach
5 and the transobturator approach as far as safety and
6 effectiveness.

7 So, ladies and gentlemen, at the end of the day on
8 the issue of whether this device is safe and, safe and
9 effective or whether it's defective, as, as the plaintiffs
10 contend, I think you're going to conclude that the device is
11 safe and it's not defective.

12 The other issue that the plaintiffs have brought up
13 is that they've criticized our warnings. Now, it's important
14 to note, and the Judge talked to you earlier, that Boston
15 Scientific's duty to warn goes to the physicians, not to the
16 patients. And there's a reason for that.

17 This is a product that is lawfully sold that has been
18 through certain procedures and it's sold in the United States.
19 And we sell it to physicians and we have warning material
20 called the DFU that goes to the physicians.

21 And these physicians don't just rely upon our warning
22 material. They are educated about these products because they
23 use them every day. They go to conferences. They read
24 journals. They read about the risks and the benefits of
25 products.

—Opening Statement - Mr. Adams—

1 So, it's not just the manual that they get from
2 Boston Scientific that they rely upon when they treat their
3 patients. They rely upon their whole clinical experience and
4 all of the scientific literature.

5 And we did tell doctors in this material, and you're
6 going to hear a lot about that later, this product is intended
7 for use only by clinicians with adequate training and
8 experience. The physician is advised to consult the medical
9 literature regarding techniques, complications, hazards,
10 associated with the intended procedures.

11 And, again, all of the articles that we talked about,
12 including the Ross study and the Cholhan study, they're out in
13 the marketplace for doctors to review. It discussed the
14 potential complications.

15 And, ladies and gentlemen, these doctors, the three
16 doctors who are the main characters of this case, these
17 doctors did discuss the complications of this procedure with
18 these ladies. And these doctors will tell you that they
19 described all of the relevant risks of the procedures to their
20 patients.

21 Here are some of the potential complications that are
22 listed in our material. It talks about, "Tissue responses to
23 the implant could include vaginal extrusion, erosion through
24 the urethra or other surrounding tissue, migration of the
25 device from the desired location, fistula formation,

—Opening Statement - Mr. Adams—

1 inflammation. The occurrence of these responses may require
2 removal of the entire mesh."

3 And, ladies and gentlemen, there's no dispute that
4 these doctors knew that mesh when it's placed inside the body,
5 it's meant to be permanent. That's the essence of the use of
6 mesh. It has small holes in it. And when it's placed within
7 the tissue, the tissue grows in between it, in between it and
8 into those holes, and that's what provides the support. And
9 the doctors knew that and they explained that to their
10 patients.

11 It talks about known risks of surgical procedures for
12 the treatment of incontinence, including pain. You're going
13 to hear that some of these ladies have complaints of pain.
14 Boston Scientific told the surgeons that this will include a
15 risk of pain -- and these doctors already knew that -- and
16 risk of infection, erosion, device migration, complete failure
17 of the procedure resulting in incontinence and mild to
18 moderate incontinence due to incomplete support or over-active
19 bladder.

20 And here's a list of the other potential
21 complications: Allergic reaction, abscess, detrusor
22 instability, pelvic and vaginal pain, dyspareunia. What's
23 dyspareunia? That's pain with sex.

24 Some of the ladies here, you've already heard
25 Mr. Love say, have complaints that after they received the

—Opening Statement - Mr. Adams—

1 Obtryx, they have pain with sex. It's right here in black and
2 white for the doctors to read and provide that information to
3 their patients. It talks about vaginal bleeding, vaginal
4 discharge, dehiscence, vaginal incision, and on.

5 And all four of these ladies signed informed consents
6 after they talked with their doctors. We probably have all
7 been through the experience of having a procedure, hopefully
8 not, but if you have or if one of your loved ones have you
9 know that doctors take a lot of time explaining the risks and
10 benefits. And ultimately if you want to ask more questions,
11 you can.

12 Ultimately, you have to sign a form, informed consent
13 basically saying that you consent to the procedure.

14 I'm not going to spend a lot of time on this, but the
15 last issue that you're going to have to address after you
16 address whether the product is defective or these warnings are
17 inadequate, you have to address the issue as to whether these
18 women's complaints are actually caused by some type of defect
19 in the product.

20 And it's important to know what you're looking at,
21 the product, you have to look at whether the product is
22 reasonably designed. Again, you have to weigh the risks and
23 the benefits of the product.

24 So, even if one of these women did develop a
25 complication from the product, that doesn't mean that the

—Opening Statement - Mr. Adams—

1 product is defective. That may mean that this person happened
2 to fall within the small group of people that experience a
3 complication. It goes back to what I talked about right at
4 the start. There is no guarantee with any type of surgery.
5 There's no guarantee with any type of drug.

6 Ms. Campbell has complaints of pain, erosion. She
7 had a minor revision and she has pain during sex. And, again,
8 I'm only bringing up these issues because that, those are the
9 claims in the case.

10 But we're going to bring out her prior conditions of
11 pain and pain with sex even before the Obtryx. And you'll see
12 that there's multiple incidents. She has the Obtryx later
13 after 2009, but even before she had multiple incidents of
14 pelvic pain, chronic pelvic pain, dyspareunia, pain with
15 intercourse, severe dyspareunia.

16 You're going to see medical reports. This one, I
17 know you can't read it. The doctor records actually before
18 she gets the Obtryx that she has pain as a result of sex like
19 she feels like she's being stabbed with a knife.

20 Here's the reference here and you'll see that. It
21 says, "In her case feels like being stabbed with a knife."
22 This is all before the Obtryx was implanted into her body.

23 After the implant you're going to hear from Dr.
24 Bhanot. And Dr. Bhanot is going to say that there is a time
25 period when he tells these ladies, he tells all patients, "You

—Opening Statement - Mr. Adams—

1 should not do certain things for a certain amount of time."

2 Dr. Bhanot believes that she engaged in intercourse
3 before the healing period was over and this caused the erosion
4 or one of the major complications that she has.

5 Ms. Wilson complains. Her complaints are pain,
6 urinary issues, and some emotional and psychological stress.
7 You're going to see information about her urinary issues and
8 that this is Dr. Bhanot's records. When she went to see him
9 he says she has had no problems post-operatively for three
10 years. She has come back to the office only one time in the
11 immediate post-op.

12 Says down here, "46-year-old female status
13 post-ureterolysis for urethral stenosis following obturator
14 tape and anterior repair. Symptoms have improved. She no
15 longer has suprapubic pain and feels that she empties her
16 bladder much better."

17 You're going to see that the doctor noted that,
18 "Patient's symptoms have completely improved regarding
19 urination."

20 You're going to also see that after this incident her
21 complaints of pain are also attributable to some other issues.

22 And you heard Mr. Love talk about that these ladies
23 do have other issues. Again, that's all part of the aging
24 process that they do have other issues. And part of your job
25 is going to be to figure out, well, is it truly related to the

—Opening Statement - Mr. Adams—

1 Obtryx or is it related to some type of pre-existing condition
2 or other condition?

3 Ms. Blankenship. She has these complaints. And
4 you're going to hear that she has a pre-existing history of
5 chronic pelvic pain, vaginal infections, dyspareunia. She
6 also had depression and anxiety before she had the Obtryx
7 implanted.

8 I don't want to belabor this point, again because of
9 the time. But, again, you will see extensive evidence showing
10 that she had some of the same complaints she's now making that
11 are related that they believe, plaintiffs believe are related
12 to the Obtryx. She had a lot of these complaints before.

13 And Ms. Tyree. Her complaints are inability to have
14 sex. She has pelvic and vaginal pain and re-occurrent SUI.

15 Again, you will hear information about prior chronic
16 pelvic pain and pain with intercourse that existed prior to
17 the implant of the Obtryx. This is brought up solely so you
18 can make a determination as to whether the Obtryx caused these
19 complaints or something else.

20 And here's information about her post-implant
21 complaints. She had no complaints of pelvic pain until almost
22 three years, greater than three years after the implant of the
23 Obtryx.

24 So, ladies and gentlemen, I know I've taken up a fair
25 amount of time and I appreciate your patience in listening to

—Colloquy—

1 me today. At the end of the day, what you're going to be
2 faced with is the proposition that these ladies, even if they
3 have experienced some type of complication, a known
4 complication, that doesn't mean that the product is defective.
5 This product -- it's going to be undisputed that the
6 mid-urethral sling, and the Obtryx is one of them, is the most
7 common and clinically accepted surgical treatment for stress
8 urinary incontinence in the world. Hundreds of studies
9 support the safety and effectiveness. And there's a high cure
10 rate with low complications.

11 You're going to see that in the literature and you're
12 going to hear that from the three doctors who treated these
13 ladies. And the device at issue has less complications than
14 alternative stress urinary incontinence surgeries.

15 So, at the end of the day, Boston Scientific will ask
16 you, based upon the evidence, to return a verdict in our
17 favor.

18 Thank you for your patience.

19 THE COURT: Ladies and gentlemen of the jury, I'm
20 going to give you a recess. While you're out, do not discuss
21 this case among yourselves or permit anyone to discuss it with
22 you or in your presence. And please be in your jury lounge at
23 20 minutes after the hour.

24 We'll stand in recess for your purposes.

25 (The jury left the courtroom at 11:05 a.m.)

—Colloquy—

1 THE COURT: Counsel, it's been brought to my
2 attention that you have an issue that you want to raise with
3 respect to the videotaped depositions that you intend to offer
4 into evidence here this morning.

5 MR. MONSOUR: Your Honor, we have -- we would like to
6 play some video depositions today involving Mr. Evan
7 Brasington who is the Vice President of the company and a Mr.
8 Rob Miragliuolo who is a Vice President of the company.

9 Boston Scientific has objected to these lines of
10 questioning. We were going to -- these have been addressed
11 preliminarily by the -- these have been addressed primarily by
12 Judge Goodwin's rulings. As you are aware, some of these were
13 brought up the other day. And, so, we are bringing these
14 issues in front of you now to discuss the relevance of the
15 ProteGen sling and why such testimony about it would be
16 relevant.

17 I would first start off, Your Honor, by noting in Mr.
18 Adams' opening he said, "The first sling that we ever sold was
19 the Advantage Lynx sling." And that's not true. The first
20 sling they sold was called the ProteGen sling and they had to
21 recall the ProteGen sling because it had numerous problems.

22 Why is that relevant here? It's relevant here
23 because they did the same testing on the ProteGen sling as
24 they did on the polypropylene slings.

25 Let me go back one step. ProteGen was made out of a

Colloquy

1 different material than the polypropylene slings. It was not
2 made out of polypropylene. It was made out of this collagen
3 infused sort of graft. But it was used for the same
4 treatment.

5 Now, what they did is they launched the ProteGen.
6 They did not do extensive testing. They did not do clinical
7 testing on the ProteGen.

8 They then did a clinical study later on, found out
9 that it was problematic, and had to recall the product.

10 At the conclusion of the ProteGen debacle, they went
11 back and they analyzed the situation and they put together a
12 ProteGen task force of which Mr. Brasington was actually a
13 member. And they went back and they looked at the ProteGen
14 issue and they said, "What should we do in the future?"

15 Well, one of the documents we want to play with Mr.
16 Brasington talks about how in the future we need to do a
17 better job of risk assessment. And then they also determined
18 in another separate document, they say, "In the future for all
19 future sling materials we will gather clinical data, clinical
20 being data that is derived from actual use inside the human
21 body."

22 Why is this important? It's important because Boston
23 Scientific looked at its past conduct as to how they bungled a
24 prior sling product. And they said, "In the future we want to
25 do certain things." In other words, they set their own

Colloquy

1 standard of care.

2 And then on their immediate next product they didn't
3 follow their own standard of care. They disregarded those
4 rules. They did not gather clinical data. And they proceeded
5 to market, as Mr. Love pointed out. They didn't do any
6 clinical trials first. They did a little biocompatibility and
7 they started selling the product.

8 And, so, what we argue is on the chart that Mr. Adams
9 showed -- and he goes back and he starts talking about the --
10 he starts talking about the timeline of the sling, the
11 timeline of polypropylene urethral slings.

12 But if you look at it -- and I'm a little far away
13 and I apologize. But if you look -- if you go back in time,
14 we need to add in a little more. And that's the ProteGen
15 story because if you look at his chart, you notice that the
16 TVT product comes out. It's around on the same time as the
17 ProteGen is on the market. And then you notice the Boston
18 Scientific Advantage sling is the last retropubic sling that's
19 to be added to the market.

20 Well, why are they the last polypropylene sling that
21 enters? It's because the company was, in essence, licking its
22 wounds from the ProteGen debacle. So, it's the first chapter
23 of the story that we would like to tell.

24 And, so, that's the basis as to why we think ProteGen
25 is relevant to these cases because it's the company itself

Colloquy

1 setting a standard of care for future slings and future sling
2 materials and then not following up with it. And that's the
3 basis of our offer, Your Honor.

4 THE COURT: Response, counsel.

5 MR. ADAMS: Yes, Your Honor.

6 I was very careful to note -- and, in fact, Mr.
7 Monsour talked about my slide and said it applied to slings.
8 I was careful to note that it is a timeline of polypropylene
9 mesh mid-urethral slings. This case is about polypropylene
10 mesh mid-urethral slings.

11 The ProteGen, as Mr. Monsour has talked about, is an
12 entirely different type of product. It is a polyester product
13 that was coated with bovine collagen and there was problems as
14 a result of that product.

15 But in no way is it relevant to the issue of the
16 safety and efficacy of polypropylene mid-urethral slings. And
17 I was very careful to walk through that history and not talk
18 about the prior history of the ProteGen or anything prior to
19 the TVT.

20 The TVT was the first polypropylene sling to come
21 out. And his argument is akin to saying that, "Well, Ford,
22 because you made a sedan in 1980 that is, for example, the
23 Focus, somehow everything you learned about in the Pinto
24 debacle in the '70s should come into evidence."

25 That doesn't come into evidence because the devices

Colloquy

1 are not substantially similar. Case law talks about if, if
2 any type of history of defects have to come in, they have to
3 be substantially similar products. These are not.

4 And then also there is a huge 403 issue. For this
5 jury to hear that we had another product made of entirely
6 different material coated with cow collagen is a total side
7 issue that should not come into this case. It's not relevant.
8 And any relevant value is far outweighed by the prejudice
9 under 403.

10 THE COURT: All right, counsel.

11 Rebuttal argument?

12 MR. MONSOUR: I would -- if you look at the -- first
13 off, we are bringing these cases under a negligence and a
14 strict liability standard. So, under negligence you would
15 want to know what a reasonably prudent manufacturer would do.

16 And I think Boston Scientific would argue that they
17 are a reasonably prudent manufacturer and that when they set
18 their own standards that those would be reasonably prudent
19 that they then breached.

20 So, I think it goes straight to the duty question for
21 your consideration as the Court. So, I think it would be
22 appropriate there.

23 Second, in the note from the ruling by Judge Goodwin,
24 he notes that in the *Ethicon* trial he did not allow the
25 ProteGen story in. But that's a different situation. He

—Colloquy—

1 notes that because they were only offering it for the fact
2 that it was their product that had been recalled. Ethicon
3 then used it and they developed the TVT.

4 This is different. They were not able in that case
5 to use it to set the standards for what the company was
6 violating because it was Ethicon versus Boston Scientific.
7 This is Boston Scientific itself. And this is a subsequent
8 Boston Scientific product.

9 So, you have a completely different scenario than
10 when the Judge did not allow it in the *Ethicon* case. That's
11 why he's asking us to bring you this evidence so I can relate
12 why it would be relevant. It's very relevant in this case
13 because -- and I can show you this. There's a key points
14 document. And if you would like me to approach, I can hand it
15 to you.

16 THE COURT: Sure.

17 MR. MONSOUR: This document, Your Honor -- where
18 would you like me to come? Right here?

19 This document is the first document, Your Honor. We
20 call this the key points document. And this document has been
21 used in numerous depositions. And it's a summary of what I
22 mentioned before.

23 It says, "In connection --" it's the part I've
24 highlighted. "In connection with any future sling materials
25 Boston Scientific will gather clinical data to assess product

—Colloquy—

1 performance in a broad spectrum of clinical situations."

2 If you turn over the page, there is a whole question
3 and answer session which talks about what the company did
4 before it put the product on the market.

5 And if you look, if you look, you can see that on the
6 second page, Your Honor, it talks about, "On what basis did
7 you make the decision to launch the product and keep it on the
8 market?"

9 And then it mentions that prior to its release and
10 answer, the product met all of the standard engineering and
11 biocompatibility testing commonly applied to implants and
12 satisfied all U.S. and European regulatory requirements.

13 Well, why is that important? Because that's what
14 they did here. They realized that in this situation by doing
15 the minimum amount of biocompatibility testing you can get a
16 product onto the market, but it's still not safe.

17 And, so, they make the conclusion, which is
18 highlighted for you on Page 1, "In the future we don't need to
19 do that anymore." And that is why this is so important. This
20 topic of ProteGen is so important. It's how should this
21 company act?

22 And to show you how specific it is, Your Honor, the
23 ProteGen -- this is not for a different type of product. This
24 is for a sling used to treat stress urinary incontinence.

25 And what they say, you can look at this document

—Colloquy—

1 because you can determine from this document that they might
2 be looking at future sling materials because they say for
3 future sling materials this bovine collagen obviously was a
4 complete disaster. And that's why they say for future sling
5 materials.

6 They were contemplating at this point in time doing
7 the Advantage sling, getting into the polypropylene market
8 because they're watching the folks at Johnson & Johnson make a
9 killing off of the TVT.

10 And, so, they say, "With future sling materials we're
11 going to test it. We're going to gather clinical data first."
12 And that's why this is so important. They set it out for
13 these very products and then they don't follow through. And
14 that's why we think it should come in, Your Honor.

15 THE COURT: All right. What is it, Mr. Adams?

16 MR. ADAMS: I just wanted to address one point. May
17 I do that, Your Honor?

18 THE COURT: Go ahead.

19 MR. ADAMS: There is no evidence that at the time
20 these statements were made that Boston Scientific was getting
21 into the sling market. There's going to be no testimony on
22 that issue at all.

23 The other thing that is really important to note
24 that, again, goes to the 403 analysis is Mr. Monsour
25 referenced this, Page 2. It says, "This product was cleared

—Colloquy—

1 by the FDA and properly launched in the marketplace."

2 Again, this highlights the prejudice for this type of
3 information involving a product that they admit is not
4 substantially similar. A substantially similar product would
5 be a polypropylene product that this case is all about.

6 So, we're talking about a product made out of
7 different material, including this bovine collagen. For it
8 then to come into evidence and us not be allowed to state the
9 fact that the FDA does not require testing would be extremely
10 prejudicial.

11 It, it highlights the prejudice because with the
12 ProteGen no testing was required. Boston Scientific before
13 the Obtryx came out with the Advantage relied upon existing
14 studies and testing. There is simply no reason why this Court
15 should allow information like this on the ProteGen to come in.

16 Again, the best example I can give you is information
17 about Ford's debacle with the Pinto somehow coming in in a
18 later case. And there's actually cases on that that talk
19 about under a 403 analysis that type of information shouldn't
20 be allowed even on the issue of punitive damages or product
21 defect or negligence.

22 Thank you for your time, Your Honor.

23 THE COURT: All right, counsel. With respect to this
24 issue, the Court addressed a motion *in limine* with respect to
25 the ProteGen device. You all have referenced it --

—Colloquy—

1 Or at least, Mr. Monsour, you've referenced it in
2 your arguments.

3 The Court wanted to see the context in which it was
4 sought to be introduced before making a final decision about
5 its admissibility.

6 There has been some opening statements and, of
7 course, there will be evidence here regarding the statement
8 that Mr. Love brought out that was given to Boston Scientific
9 regarding clinical testing.

10 This statement with respect to a different device --
11 and I think to some extent it's being argued much more narrow
12 than it is, that in connection with any future sling materials
13 Boston Scientific will gather clinical data to assess product
14 performance in a broad spectrum of clinical situations.

15 I find that this is, in fact, relevant information.
16 I further find that it is admissible given the statement
17 that's going to be offered. It goes to the knowledge of the
18 defendant. It also is evidence that would go to punitive
19 damages if punitive damages are ultimately proven. This is an
20 issue that can go to punitive damages given the elements that
21 the plaintiff is required to prove in order to get punitive
22 damages to the jury.

23 And I find, given the nature of this case, given that
24 warnings and the fact that a defective device was given to
25 these plaintiffs through their physicians that this is

—Colloquy—

1 admissible.

2 I further find that in light of that that its
3 probative value is not substantially outweighed by any undue
4 prejudice.

5 And, so, I am going to allow the evidence, preserving
6 the defendant's objection and exception. And I am willing,
7 counsel, to give an instruction regarding its limited purpose
8 if requested to do so.

9 MR. ADAMS: We would, Your Honor, and we'll prepare
10 that. I might make one request.

11 THE COURT: Yes, sir.

12 MR. ADAMS: This document is Exhibit 53 on key
13 points. The -- I would suggest that the Court only allow in
14 the first page and not the information about the recall of the
15 ProteGen.

16 Again the Q and A that follows, there are multiple
17 references to the FDA and the clearance process for -- the
18 fact that we are not allowed to bring up the fact that the
19 Obtryx was cleared by the FDA, for then this document to come
20 in as is I think again would be extremely prejudicial and
21 confusing.

22 And I think, frankly, it should open the door -- if
23 this came in, it should open the door to the fact that the
24 Obtryx was cleared, which I know Judge Goodwin has already
25 ruled upon.

Colloquy

1 So, again, for the purpose that the Court is allowing
2 this document to come in, I think the first page suffices to
3 reduce the prejudice.

4 THE COURT: The Court has previously ruled with
5 respect to any FDA regulations. And, of course, I'm going to
6 follow that and keep it --

7 Mr. Monsour.

8 MR. MONSOUR: We will redact out the FDA portions,
9 Your Honor. We anticipated this. We will not cross the FDA
10 line and violate Judge Goodwin's rulings I promise you.

11 THE COURT: All right. I want to see what your
12 redactions are and I'll give you a final ruling on the
13 document. Let's take a break until about 11:30 and come back.

14 (A Recess was taken from 11:23 a.m. to 11:34 a.m.)

15 THE COURT: Plaintiff, call your first witness,
16 please.

17 MR. LOVE: Your Honor, at this time plaintiffs would
18 call Evan Brasington, Boston Scientific's vice-president of
19 worldwide marketing.

20 THE COURT:

21 MR. LOVE: And the video cut is 32 minutes.

22 THE COURT: All right. Ladies and gentlemen, you
23 will recall that those witnesses who appear by video, you are
24 to assess their credibility the same as you would and to view
25 their evidence the same as you would if the person appeared

—Evan Brasington - By Video—

1 here in person before you.

2 (The video testimony of EVAN BRASINGTON was played
3 from 11:35 a.m. to 12:07 p.m.)

4 MR. LOVE: That concludes plaintiffs' proffer, Your
5 Honor, for Evan Brasington.

6 THE COURT: All right. Mr. Strongman?

7 MR. STRONGMAN: Boston Scientific has about a
8 19-minute offer for Mr. Brasington.

9 THE COURT: All right. Thank you.

10 (The video testimony of EVAN BRASINGTON continued at
11 12:08 p.m. to 12:28 p.m.)

12 MR. STRONGMAN: That concludes Boston Scientific's
13 offer on Mr. Brasington.

14 THE COURT: All right. Thank you, Mr. Strongman.

15 Ladies and gentlemen, I'm going to give you your
16 luncheon recess. While you are out, do not discuss this case
17 among yourselves or permit yourself -- or permit anyone else
18 to discuss it with you or in your presence.

19 Please be in your jury lounge at 1:30. We will stand
20 in recess.

21 COURT SERVICES OFFICER: All rise. This Court is in
22 recess.

23 (The Jury left the courtroom at 12:28 p.m.)

24 (A luncheon recess was taken at 12:29 p.m.)

25 (The Jury entered the courtroom at 1:30 p.m.)

—Charles Smith - By Video—

1 THE COURT: Good afternoon, everyone.

2 Counsel, call your next witness, please.

3 MR. LOVE: Your Honor, at this time we would call
4 Boston Scientific employee Charles Smith who was the Director
5 of Development/Sustaining Research, and that video clip is 11
6 minutes and 41 seconds.

7 THE COURT: All right.

8 MR. LOVE: Looks like we are having a technical
9 difficulty, Your Honor, with some audio. If you give us just
10 two seconds, I think we can clean it up.

11 THE COURT: Yes, sir.

12 MR. LOVE: With the Court's permission, we can
13 certainly call Peggy Pence now live and then fix this maybe at
14 a break and then play videos this afternoon.

15 THE COURT: All right.

16 (Audio began.)

17 MR. LOVE: (Indicating.)

18 (The video testimony of CHARLES SMITH, JR., was
19 played at 1:35 p.m.)

20 MR. LOVE: That concludes the plaintiffs' portion of
21 the depo.

22 THE COURT: Mr. Strongman?

23 MR. STRONGMAN: Nothing further from Boston
24 Scientific at this time.

25 THE COURT: All right. Thank you. Call your next

—Pence - Direct - Love—

1 witness, please.

2 MR. LOVE: The plaintiffs would call Dr. Peggy Pence.

3 THE COURT: Dr. Pence, will you come up and take an
4 oath or affirmation, please?

5 THE WITNESS: Yes, ma'am.

6 THE DEPUTY CLERK: Would you please raise your right
7 hand.

8 (**PEGGY PENCE, Ph.D.**, HAVING BEEN DULY SWORN, TESTIFIED AS
9 FOLLOWS:)

10 THE WITNESS: Yes, I swear.

11 THE DEPUTY CLERK: Please take stand.

12 THE WITNESS: Thank you.

13 THE COURT: Counsel, let me see you here, please, at
14 the bench.

15 MR. LOVE: Sure. Your Honor, may I bring Dr. Pence a
16 glass of water?

17 THE COURT: Yes, sir.

18 (The following occurred at sidebar.)

19 THE COURT: I don't know if there are documents that
20 you plan to use that have not been admitted, but I don't want
21 the jury shown anything that's not being admitted unless there
22 is an agreement between the two of you that there is no
23 objection to its admission. The clerk has control of these
24 other screens, of course, not for the large screen, so I want
25 you all to be careful about what goes to the jury.

—Pence - Direct - Love—

1 MR. LOVE: How would you like me to handle that? Say
2 Exhibit Number 233, do you have any objection -- I would like
3 to offer 233 and I have got copies for both of you. I
4 apologize. I didn't bring it.

5 THE COURT: I want them to be admitted before they
6 are shown to the jury.

7 MR. LOVE: Okay.

8 THE COURT: So that's fine, if there is an agreement
9 that there is no objection.

10 MR. ADAMS: I don't know what he's going to --

11 MR. LOVE: I will give both of you a notebook as soon
12 as I head back there. With respect to studies, do I just ask,
13 may I publish Exhibit 234 which is a study?

14 THE COURT: I want to know if there is an objection
15 before anything is shown to the jury.

16 MR. LOVE: Absolutely.

17 MR. ADAMS: I wanted to add, too, this, as you're
18 aware, Judge, this expert, this is a professional expert,
19 there was a *Daubert* ruling by Judge Goodwin. He basically
20 allowed her to testify about one opinion: Should premarket
21 clinical testing have been done? Now I'm getting an inference
22 that she may be looking at studies done that was after we
23 launched it. I don't think -- again --

24 THE COURT: He has precluded any postmarket studies,
25 and he's also precluded any opinions with respect to

—Pence - Direct - Love—

1 marketing. Those are the two -- or labeling, I'm sorry.
2 Those are the two opinions that he has excluded with respect
3 to Dr. Pence.

4 MR. ADAMS: Yeah. The only opinion she can give is
5 whether we should have done premarket clinical studies. So
6 what I'm alerting the Court to, I don't know what counsel
7 plans to do, but I would think that that is a pretty limited
8 area that she can testify to.

9 MR. LOVE: Just so the record is clear, if you look
10 at his order specifically, he specifies pages within the
11 report that he found acceptable for the testing opinion that
12 she's going to offer. Some of those studies postdate
13 marketing but predate any -- they were not marketed to my
14 client specifically. My client's surgeries are in 2009, '10
15 and '11. And so the marketing, the premarketing testing
16 opinions, I don't think are limited.

17 In fact, he specifically cites pages that he
18 authorizes her to testify on, where studies do postdate the
19 marketing of this particular product. What he specifically
20 allowed her to do was talk about the test date, whether it was
21 appropriate based upon what was feasible at the time. And
22 what's important with respect to what they could have done
23 prior to marketing is that they actually performed studies
24 that could have been done premarketing, had they done -- the
25 scientific technology was available to do the exact things

—Pence - Direct - Love—

1 she's going to say should have been done.

2 THE COURT: I don't know, but the jury is here. Both
3 of you have the judge's opinion, and I'm going to expect you
4 to live within the confines of it. If you hear something,
5 Mr. Adams, that you have objection to that the Court has
6 excluded, I will deal with it. It may be that you don't hear
7 anything. I expect you both to live within the confines of
8 the judge's ruling.

9 MR. LOVE: Absolutely.

10 MR. ADAMS: And, Your Honor, I wanted to give you an
11 example. If she starts going into studies, like the Ross
12 study or the Cholhan study, I think that's clearly beyond
13 premarket. She can say those -- a type of randomized clinical
14 trial should have been done, but she can't talk about our
15 studies, and I don't know if you're going to go there.

16 MR. LOVE: I think she can. I think she can say the
17 Ross study is a randomized controlled trial, and it was done
18 in 2009, and talk about fact that it was scientifically
19 feasible for this company to perform that very study prior to
20 marketing. Her whole opinion is they should have done a
21 randomized controlled trial but they were not capable of doing
22 it.

23 MR. ADAMS: She doesn't need to reference Ross or any
24 of the other studies. She can talk about -- again, he allowed
25 her opinion on the limited issue of what -- Boston Scientific

—Pence - Direct - Love—

1 should have done premarket clinical testing. She can say that
2 should have been a randomized clinical controlled trial, but
3 there is no need -- and Judge Goodwin is not allowing her to
4 testify about actual studies.

5 MR. LOVE: She has been -- go ahead. I'm sorry.

6 THE COURT: He sets forth, gentlemen -- maybe you all
7 need to go back and read it, but he sets forth the opinion on
8 58 of his ruling. He then goes into the argument that's been
9 made by both of you. He ultimately agrees with the plaintiff
10 that this opinion does not have the same problems it did in
11 the previous case where he excluded it. He indicates that
12 that opinion -- the motion is denied, he grants the opinion --
13 or the motion as to postmarketing and as to the labeling.
14 That's what I see here. And so I think that she's permitted
15 to give this opinion, Mr. Love.

16 MR. LOVE: All right.

17 THE COURT: And I preserve an objection and exception
18 to you if you have some quarrel with the Court's
19 interpretation of that ruling.

20 MR. LOVE: Thank you.

21 MR. ADAMS: Okay.

22 (Sidebar concluded.)

23 MR. LOVE: Your Honor, would the Court like a copy so
24 you can follow along as well? These are going to be exhibits
25 that may be discussed during her testimony.

—Pence - Direct - Love—

1 THE COURT: All right. Thank you.

2 MR. LOVE: May I approach?

3 THE COURT: Yes. Thank you.

4 MR. LOVE: Thank you.

5 Your Honor, one last final request, is it possible
6 that we can get that screen turned on? I think you have to do
7 it from where you're at or someone.

8 THE COURT: Counsel, in our discussion here, I want
9 to also make sure you all understand that I of course, did not
10 intend to exclude the basis of this opinion.

11 MR. LOVE: Oh, I apologize. I couldn't --

12 THE COURT: It was not my intention during our
13 discussion here at the bench to exclude the basis of this
14 opinion.

15 MR. LOVE: Sure, thank you, Your Honor.

16 THE COURT: All right.

17 MR. LOVE: Your Honor, may I proceed?

18 THE COURT: Yes, sir.

19 (DIRECT EXAMINATION OF PEGGY PENCE, Ph.D. BY MR. LOVE:)

20 Q. Good afternoon, Dr. Pence.

21 A. Good afternoon, Mr. Love.

22 Q. How are you doing?

23 A. I'm doing fine. Thank you. How are you?

24 Q. I'm fine, thanks. We've got a tough job this afternoon.
25 We've got to kind of keep this jury entertained after lunch

—Pence - Direct - Love—

1 when everybody kind of gets tired.

2 Would you please introduce yourself to the jury?

3 A. Good afternoon. My name is Peggy Pence. Nice to meet
4 you all.

5 Q. Okay. Are you a doctor, a Ph.D. doctor?

6 A. Yes, I am.

7 Q. Do you mind if I call you doctor?

8 A. No, that would be fine, thank you.

9 Q. Dr. Pence, tell the jury what you do for a living.

10 A. I am a consultant to the medical device and
11 pharmaceutical industry, and I help them to develop the
12 strategy for marketing their products when they have a new
13 product idea, and help them to determine the types of testing
14 that they will need to do, both what we call preclinical and
15 also clinical testing prior to marketing, that will enable
16 them to be able to market their product.

17 Q. Okay. Let's talk a little bit about your education. You
18 do have an undergraduate degree?

19 A. I do.

20 Q. All righty. And what is your undergraduate degree in?

21 A. It's in microbiology.

22 Q. Okay. Where did you get that degree?

23 A. Louisiana Tech.

24 Q. Perfect, perfect. Okay. And do you have any graduate
25 degrees?

—Pence - Direct - Love—

1 A. I do.

2 Q. All right. You said microbiology, your undergraduate
3 degree?

4 A. That's correct.

5 Q. What is microbiology?

6 A. It's the study of microorganisms, bacteria, viruses.

7 Q. And you do have, you said, a graduate degree?

8 A. I do.

9 Q. And in what?

10 A. My major is pharm -- is toxicology and my minor,
11 pharmacology.

12 Q. And real briefly, you have a Ph.D. in toxicology, I
13 understand?

14 A. That's correct.

15 Q. What is toxicology?

16 A. Toxicology is basically the study of poisons, and as it's
17 applied to the medical device industry and the pharmaceutical
18 industry, it's looking at the adverse effects, the potential
19 toxicity of medical devices, the materials that medical
20 devices are made of, or the adverse effects from drugs.

21 Q. Okay. Let's talk a little bit about your experience.
22 Have you ever worked for a pharmaceutical or medical device
23 company?

24 A. Yes.

25 Q. All right. Let's take a look at this slide here. Let me

—Pence - Direct - Love—

1 get this thing to work. There you go.

2 I have on this slide, I pulled some information off of
3 your C.V., and I just wanted to summarize it for the jury's
4 benefit. Are these some of the companies that you've worked
5 for over the past 30 years?

6 A. Over the past 40 years.

7 Q. Over the past 40 years, I'm sorry.

8 A. Over 40 years actually.

9 Q. I was trying to protect your age.

10 A. Thank you. I appreciate that.

11 Q. So it looks like from 1970 to approximately 1992, you
12 worked at a number of different pharmaceutical and/or medical
13 device companies?

14 A. That's correct.

15 Q. If you could, just explain to the jury what types of jobs
16 you held at each of these types of companies.

17 A. I held a variety of jobs. When I first started out at
18 Eli Lilly and Company, I was working in the basic research
19 laboratory, developing methodologies for testing potential new
20 drugs to see if they might have a purpose or -- for treating
21 immunological diseases, and from there I moved into clinical
22 testing.

23 And from there, I moved to Serono Laboratories where I
24 had responsibility for managing clinical trials, for designing
25 and managing clinical trials, and at Triton Biosciences, I

—Pence - Direct - Love—

1 held a project management position, and what I did there was
2 to oversee all aspects of product development.

3 At that point I had realized that I wanted to have my
4 own business someday, and so I wanted to understand the full
5 process of product development better. So as a project
6 manager, I worked with people in manufacturing, through
7 preclinical testing, clinical testing, all the way through,
8 working with people that would be watching a product, should
9 we be able to prove safety and effectiveness for marketing.
10 And then at Amgen, I was responsible for clinical trials.

11 Q. Perfect, perfect. Now, you said a number of things that
12 I would be interested in and I think the jury might be
13 interested in as well, but I want to take this one step
14 further.

15 You said you started at your own company. What's the
16 name of your company?

17 A. Symbion Research International.

18 Q. Okay. And Symbion Research International is identified
19 here. Explain to the jury the types of work that your company
20 does.

21 A. As I mentioned, we're a consulting and contract research
22 organization. We work with different companies, medical
23 device, pharmaceutical companies, who identify a product
24 that -- that they would like to take to the market, and help
25 them to do various aspects of product development, in

—Pence - Direct - Love—

1 particular, helping them to determine what types of testing
2 they'll need, both preclinically and clinically, and then
3 helping them to design the studies and overseeing the conduct
4 of those studies, amongst other types of activities.

5 Q. Perfect, perfect. Okay. And it looks like you do
6 consulting work currently for pharmaceutical companies, is
7 that fair?

8 A. That's correct.

9 Q. Biopharmaceutical companies, is that fair?

10 A. That's correct.

11 Q. As well as medical device companies?

12 A. That's correct.

13 Q. And you do that in all areas of product development?

14 A. That's correct.

15 Q. Okay. We're going to talk about product development in
16 just a minute, but the last thing here is litigation support.
17 When did you start doing this type of work?

18 A. About five to six years ago.

19 Q. Okay. Why did you get interested in this type of work?

20 A. I was first contacted to -- to work with attorneys that
21 were involved in some product liability cases, and about
22 five -- about six years ago, actually, and decided that this
23 is an extension of my teaching. I -- over the years, I've
24 been in this industry for over 40 years, and I think it's
25 important to share the knowledge and experience and hopefully

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1 wisdom that I've gained over those periods of years through
2 teaching.

3 So I teach students and from -- with different
4 backgrounds at this point in time, and I see this as really as
5 an extension of teaching, sharing the knowledge and hopefully,
6 again, the wisdom that I've gained over the years to let
7 others understand about product development, the types of
8 testing that goes into products that are marketed for medical
9 conditions.

10 Q. Okay. Fair enough, fair enough. Let's talk about
11 product development. That's kind of why you're here today,
12 right?

13 A. Yes.

14 Q. Okay. Product development, what does that encompass and
15 walk through it. I know this slide isn't the best slide
16 because I think if we were being accurate, all of these little
17 bullet points would be within the bailiwick of product
18 development, fair?

19 A. That's correct.

20 Q. Okay. If we could, walk the jury through what product
21 development entails and why it's important when you're putting
22 new medical devices on the market.

23 A. Well, product development encompasses all aspects of
24 design and testing that need to be accomplished in order to
25 get a product on the market. So from the manufacturing

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1 process and in the case of a medical device, from designing
2 it, understanding what user needs are, what is the product
3 going to be used for? And then designing the product to meet
4 that need.

5 And once you've designed the product, you have to test
6 it to find out -- to determine does it meet the needs for
7 which you're developing it? Can it be used in -- for the
8 intended use, again, for what you're developing it?

9 And then the preclinical testing and the clinical
10 testing are -- you do the preclinical testing first before you
11 go into the clinical testing, again, are confirming that the
12 product is safe and effective for the use for which you intend
13 it.

14 Q. Okay. Let's talk about two other quick points.

15 Preclinical and clinical testing. The jury has heard these
16 terms in opening statements and may have heard it through one
17 of the witnesses they've seen already. What is preclinical
18 testing? How is that defined?

19 A. Preclinical testing is the testing that is done prior to
20 testing in humans. And sometimes we also continue preclinical
21 testing after one starts into human clinical trials, depending
22 on what the project may be. But there are certain tests that
23 you must do before you put a product into humans because you
24 have to justify that the product is safe enough and has a
25 potential benefit for humans before you subject humans to the

—Pence - Direct - Love—

1 potential risks of giving -- using a new product on them. And
2 preclinical includes laboratory testing, that can be in a test
3 tube type situation, or in animals.

4 Q. Okay. Let's talk about clinical trials and explain just
5 briefly what a clinical trial is.

6 A. Clinical trial is testing in humans.

7 Q. Okay. And I've heard the term randomized controlled
8 trial. What is that?

9 A. A randomized controlled trial is what we call the gold
10 standard or best evidence kind of a study that's done because
11 subjects, humans, are randomly allocated to a treatment. In a
12 randomized controlled trial, the purpose of that trial is to
13 compare two or more different treatments. And because you're
14 randomly assigning patients to treatment, the purpose of that
15 is to reduce bias in the trial.

16 Q. And in reducing bias, that's why it's kind of considered
17 the best type of evidence to establish safety and efficacy?

18 A. That's correct, the data is most reliable.

19 Q. Okay. We're going to focus most of our time here today
20 talking about premarket testing that could or should have been
21 done, but I want to finish up with your background real quick,
22 if we could.

23 Do you serve on any boards or hold any memberships in
24 organizations that are relevant to your opinions in this case?

25 A. Yes, I have in the past and do currently.

—Pence - Direct - Love—

1 Q. Okay. Tell the jury about a few of those so they can
2 kind of get a feel for who you are.

3 A. I participated in the Clinical Trial Program Certificate
4 Advisory Board through California State University at the
5 Fullerton campus to develop a certification program in
6 clinical trials for people with appropriate backgrounds who
7 might be interested in working in clinical development. So
8 hopefully by completing a certification program, that would
9 not only give them the background information they need, but
10 enable them to get a job in the industry, in doing clinical
11 trials.

12 I also have served on the Biotechnology and Healthcare
13 Advisory Board in California State University on the Channel
14 Islands campus. And I served on a nonprofit board as well for
15 the, what used to be the CareNow Foundation is now called the
16 CompassioNow Foundation.

17 Q. And what is the CompassioNow Foundation briefly?

18 A. CompassioNow is, again, as I mentioned, a nonprofit, and
19 our mission is to provide medical care to the world's least
20 served. We've been principally working in various countries
21 in Africa, Uganda, Tanzania, Zambia, and funding local clinics
22 and also a Mission Medic Air, a flying clinic, if you will,
23 for outreach to communities that are very rural, and providing
24 us medical supplies, both medicines and equipment, and funding
25 for doctors and nurses for those clinics.

—Pence - Direct - Love—

1 Q. Okay. Last topic on your experience, teaching
2 experience, do you have any?

3 A. Yes, I do.

4 Q. Okay. Tell the jury a little bit about your teaching
5 experience as it pertains to the issues involved in this case.

6 A. In -- I mentioned the Clinical Trials Certificate Program
7 Advisory Board on which I served. I also went on to develop
8 one of the courses for that certificate program on clinical
9 trials project management, and taught that at California State
10 University, Fullerton campus, and I have now for several years
11 been part-time faculty at the California State University,
12 Channel Islands campus, teaching graduate students in
13 biotechnology a course on clinical trials and quality
14 assurance.

15 Q. Okay. And who are your students over the years, who have
16 you taught?

17 A. I've taught both industry professionals and graduate
18 students in the healthcare field.

19 Q. So you've actually taught industry professionals or
20 employees of medical device companies about the very issues
21 you're going to talk about today?

22 A. Yes. In addition to the -- the university teaching that
23 I've done, I've also done a number of different workshops at
24 companies and chaired conferences and given speeches in the
25 area, some of the areas that we're talking about today.

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1 Q. Okay. Perfect. Well, let's get into the work you've
2 done in case. What did I ask you to do in this case,
3 Dr. Pence?

4 A. You asked me to perform an investigation to determine
5 whether or not Boston Scientific Corporation had done the
6 appropriate testing of its Obtryx sling for marketing of the
7 product.

8 Q. Okay. And we'll get to that opinion in just a minute,
9 but what types of materials did you need to review in order to
10 complete your investigation?

11 A. I reviewed a large variety of materials, including many
12 corporate documents, various types of reports, e-mails,
13 internal correspondence, numbers of different types of
14 documents, as well as a number of different depositions of
15 employees and other people involved in -- with Boston
16 Scientific in the development of its sling products as --

17 Q. Let me stop you right there, okay, because you mentioned
18 a few things, and I want to just break this down a little bit.
19 You had to review internal documents?

20 A. That's correct.

21 Q. Internal documents, you mean documents that Boston
22 Scientific has produced in this litigation?

23 A. That's correct.

24 Q. Okay. And then you said depositions?

25 A. That's correct.

—Pence - Direct - Love—

1 Q. Are you talking about depositions of Boston Scientific
2 employees?

3 A. That's correct.

4 Q. Okay.

5 A. And other related --

6 Q. We're going to get there.

7 A. Okay.

8 Q. What about -- what is it about the depositions and the
9 internal documents that were important in your investigation?

10 A. In order to do an appropriate investigation, I have to go
11 back in time and get an insider's look. I need to know the
12 what, when and why. I need to know what was known, when it
13 was known, and what decisions were taken by key personnel and
14 why those decisions were taken.

15 Q. Okay. Fair enough. Fair enough. Scientific literature,
16 was it necessary for you to evaluate the available scientific
17 literature?

18 A. Yes, definitely.

19 Q. And why is that important in your investigation?

20 A. The scientific literature is important for a couple of
21 reasons. The first is I needed to see if there's any
22 information or any publications available in the scientific
23 literature about the Obtryx sling. Have any tests been done
24 and published on the Obtryx sling? I needed to know that
25 information.

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1 Secondly, I need to know, for different products that
2 might have -- that would be used for the same purpose or
3 similar type of mesh but different, for example, I also needed
4 to know what information is known about those, what kinds of
5 problems, issues there may have been, whether or not they were
6 effective as well.

7 Q. Okay. So we've got scientific literature, we've got
8 depositions, we've got internal documents. Was there any
9 other information that was necessary for you to complete your
10 investigation in this case?

11 A. I did some of my own independent research, definitely.

12 Q. Okay. Perfect, perfect. Now, have you completed your
13 investigation?

14 A. Yes, I have.

15 Q. All right. Have you formed opinions in this case?

16 A. Yes, I have.

17 Q. And what is your opinion with respect to what I've asked
18 you to do?

19 A. My opinion is that Boston Scientific failed in its
20 responsibilities as the manufacturer of the Obtryx sling to
21 perform the appropriate testing for marketing of the Obtryx
22 sling.

23 Q. Okay. All right. Well, let's explore that opinion, if
24 we can.

25 Let's talk about the testing that's available and the

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1 testing that you deem is appropriate in this case.

2 In your experience, what types of tests or studies are
3 necessary to ensure that a product is safe before it is made
4 available for sale for a permanent implantation?

5 A. There are a variety of different types of studies that
6 are -- that are required, that are necessary.

7 Q. In this case, with respect to the Obtryx sling, what's
8 your opinion with respect to what types of testing should have
9 been done?

10 A. In addition to bench testing and biocompatibility
11 testing, there should have been additional testing in animals,
12 as I was explaining, and then human testing.

13 Q. Okay. And is it your -- is your opinion that there
14 should have been randomized controlled trials in humans before
15 it was made available for sale?

16 A. Yes. Definitely.

17 Q. And, just briefly -- actually, let's just back up and go
18 through the testing and we'll get to the why in a minute.

19 A. Okay.

20 Q. So we talked about the different types of testing and
21 let's just go ahead and -- you're familiar with the different
22 types of testing described here?

23 A. Yes.

24 Q. All right. And the jury has heard, I think, all of these
25 so far, but I just want to touch on each of them so they can

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1 get an idea of kind of the purpose behind each type of
2 testing, if we could.

3 Let's talk about bench testing. What does this tell
4 us?

5 A. Bench testing basically tells us whether or not the
6 medical device is going to function properly. I mentioned
7 when you design a product, you establish specifications that
8 it needs to meet to meet user needs, and the bench testing
9 talks -- tests to determine whether or not it will meet those
10 user needs, things like, is it strong enough, is it too stiff,
11 does it tear when it's under too much tension.

12 Q. Okay. Perfect, perfect. Now, this bench testing that's
13 done, is it done in humans?

14 A. No.

15 Q. It's done in a laboratory?

16 A. That's correct.

17 Q. Okay. Let's talk about biocompatibility testing. Just
18 briefly explain what the -- what the purpose of
19 biocompatibility testing is.

20 A. Biocompatibility testing is done to determine or predict,
21 if you will, how the medical device, how the materials in the
22 medical device may interact with the human body. And it,
23 however, doesn't determine biocompatibility because it's not
24 done in humans. So, but it is an important step to the next
25 steps, over the next phases of testing, further animal testing

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1 and then human testing, as a mentioned.

2 Q. Real quick, let's back up. You said, I believe,
3 biocompatibility testing can establish how a device may
4 interact with the human body?

5 A. Yes, that's correct. It gives some information about how
6 it may interact.

7 Q. Can it establish how it will interact with the human?

8 A. No, it cannot.

9 Q. How do you establish how a product will interact in a
10 human body?

11 A. By testing it in humans.

12 Q. Perfect, perfect. Animal studies, let me ask you this:
13 Did Boston Scientific perform any bench testing on the Obtryx
14 sling?

15 A. Yes.

16 Q. Okay. What types of bench testing did it perform?

17 A. They did tensile strength, burst strength, the pore size
18 of the mesh, various tests of that nature.

19 Q. Okay. Biocompatibility testing, did they perform any on
20 the Obtryx sling?

21 A. Not on the Obtryx sling specifically. For the
22 biocompatibility, they relied on biocompatibility testing that
23 was done on a polypropylene mesh over ten years before the
24 marketing of the Obtryx sling.

25 Q. Was that, like, in 1992 or so, is that --

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1 A. 1992, 1993, that's correct.

2 Q. Perfect, perfect. Now, in the absence of human testing,
3 can bench testing or biocompatibility testing ever establish
4 that a product is safe for permanent implantation in humans?

5 A. No, it cannot.

6 Q. Okay. Let's talk about animal testing, but let's go back
7 to testing. In the United States, who's responsible for
8 ensuring that testing is done to establish that a product is
9 safe?

10 A. That is the manufacturer of the product.

11 Q. Okay.

12 A. Boston Scientific --

13 Q. Okay.

14 A. -- in this case.

15 Q. Okay, okay. Now, is this a shared responsibility with
16 anyone?

17 A. No, it is not.

18 Q. It's their responsibility, correct?

19 A. That is correct.

20 Q. All right. Is it okay for a company like Boston
21 Scientific to rely upon the testing done on other products
22 made by other companies?

23 A. No. That other testing is important, as I mentioned,
24 reviewing the literature. It's important to what you can be
25 aware of to know that information so that it informs the type

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1 of testing, you get that knowledge, and you apply it to the
2 development of your product. So it's important to know that
3 and factor it into your own testing and development, but it
4 can't tell you how your product will perform.

5 Q. Okay. Last two, real quick. Animal testing, what's the
6 purpose of animal testing? What is that supposed to give us
7 insight on?

8 A. Animal testing is the next step in order to, again,
9 determine that the product has a reasonable likelihood of
10 working in humans, and, more importantly, that it -- it is
11 safe enough to be able to take it into human testing. You
12 don't want to expose humans to undue risk.

13 So it's a gradation, it's a stepwise process of
14 testing, so that by the time you get to humans, you hope that
15 you have established that the product will not cause any undue
16 harm. It doesn't always work that way, sometimes we do see
17 harm in humans, with testing, but the whole -- in clinical
18 trials. But the purpose is to do all we can to determine that
19 it's safe enough for testing in humans before we put it into
20 humans.

21 Q. Perfect, perfect. Thanks for your time on these issues.

22 Okay. We are done with the testing now. Let's go on
23 to the Obtryx sling itself.

24 The jury has heard from Evan Brasington about the
25 ProteGen sling story. Why is that story important to your

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1 opinions in this case?

2 A. It's important because that was a sling that preceded the
3 development of the Obtryx sling, and I'm not sure what you
4 heard, but that product had some safety issues that caused the
5 company to cease marketing of that product. So they were
6 aware that -- and that product had not gone through clinical
7 testing. So they were on notice, if you will, they understood
8 that by not doing clinical testing before marketing a product,
9 that serious safety issues can arise.

10 Q. Well, let me ask you this: Have you reviewed as part of
11 your investigation any evidence to it where Boston Scientific
12 assessed whether it was appropriate to do or not do clinical
13 testing prior to the launch of their next product?

14 A. Yes, I have.

15 MR. LOVE: At this time, Your Honor I would like to
16 offer Exhibit 759 which is, I believe, the second tab in your
17 notebook and the second tab in yours, Mr. Adams.

18 THE COURT: Objection, Mr. Adams?

19 MR. LOVE: It would just be the first page.

20 MR. ADAMS: Just the -- just Page 261?

21 MR. LOVE: That's correct.

22 MR. ADAMS: Your Honor, I'd note my earlier
23 objection.

24 THE COURT: All right. And it's under which tab,
25 counsel?

—Pence - Direct - Love—

1 MR. LOVE: It's under Tab 759, Your Honor.

2 THE COURT: All right. I will order that this
3 document be admitted, preserving the defendant's objection and
4 exception, based on my earlier reasoning, counsel.

5 MR. LOVE: Thank you, Your Honor.

6 (PLAINTIFF EXHIBIT P-759 WAS RECEIVED IN EVIDENCE.)

7 (The document was published to the jury.)

8 MR. LOVE: I pulled it up. Let me see if I can go
9 ahead and do that.

10 BY MR. LOVE:

11 Q. Okay. This is a document you have reviewed as part of
12 your investigation, is that correct, Dr. Pence?

13 A. Yes, it is.

14 Q. Okay. And what is this document, for the jury's benefit?

15 A. This is a key learning point document based on the
16 company's experience with the ProteGen sling.

17 Q. Okay. Let me just go ahead and read it because it's not
18 the best quality copy. It says, "Boston

19 Scientific/Microvasive decided to voluntarily discontinue
20 marketing the ProteGen sling because we could not assure

21 ourselves that it was producing outcomes consistent with
22 Microvasive's standard of performance for its products and
23 because of the variability of outcomes among different
24 centers." Did I read that correctly?

25 A. Yes, you did.

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1 Q. And the last point is, "In connection with any future
2 sling materials, Boston Scientific will gather clinical data
3 to assess product performance in a broad spectrum of clinical
4 situations."

5 Now, why are these findings and these conclusions
6 important to your opinions as it pertains to the Obtryx sling?

7 A. Well, once again, it shows that the company understood
8 that they did not do appropriate clinical testing for the
9 ProteGen sling and, as a result, encountered problems. There
10 were safety issues, people were being harmed. And so the
11 product was taken off the market.

12 So with that knowledge, that was knowledge they had,
13 that clinical testing is needed to determine safety before
14 they tested the Obtryx sling and marketed it. I mean, before
15 they marketed the Obtryx sling.

16 Q. What was the date of this investigation, just for the
17 jury's benefit, can you see it up there?

18 A. Yes. 1999.

19 Q. Okay. So that was roughly five years before the Obtryx
20 sling was made available?

21 A. That's correct.

22 Q. Okay. Perfect. Let's talk about the Obtryx, if we can.

23 Obtryx, I think it was August, 2004, is that when it
24 was made available for sale?

25 A. That's correct.

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1 Q. Okay. Perfect, perfect.

2 The Obtryx sling, how was it different, if it was, from
3 previous sling product made by other companies?

4 A. Made by other companies?

5 Q. Yeah.

6 A. The -- has the jury seen an Obtryx sling?

7 Q. Oh, they have. In fact, let me get that. Would this
8 help demonstrate your testimony if you were able to have this?

9 A. Yes.

10 MR. LOVE: May I approach the witness, Your Honor?

11 THE COURT: Yes, sir.

12 BY MR. LOVE:

13 Q. Just use it at your convenience.

14 A. Thank you.

15 So assuming you've seen this earlier, earlier today,
16 this is the polypropylene mesh sling. It's about 17 to 18
17 inches long. And this center section that sits under the
18 urethra -- and forgive me if I'm repeating things you've
19 already heard, but since I'm not sure what you may have
20 heard -- the sling sits under the urethra. The urethra is the
21 tube through which you urinate. And the center section of
22 this is what they call detang. There is about a little over
23 one-half inch piece of the center of it that is detanged.

24 If you were able to feel the edges of this, the center
25 section feels differently because they've heat sealed those

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1 edges. And the idea for that piece that sits under the
2 urethra is that with the heat sealing of those edges, that it
3 would resist being distorted when tension is applied during
4 surgery to appropriately tension it so it has the right amount
5 of tension to stop -- to stop the stress urinary incontinence.
6 And, also, that it would be -- the hope was that it would be
7 less irritative to the urethra and hopefully decrease the
8 likelihood of erosion of the sling into the urethra.

9 Q. Perfect, perfect. Okay.

10 So the design change made by Boston Scientific was this
11 detangling or heat sealing?

12 A. That's correct.

13 MR. ADAMS: Objection, Your Honor. May we approach?

14 THE COURT: Yes, sir.

15 (The following occurred at sidebar.)

16 MR. ADAMS: I object to the testimony. It's outside
17 the scope of the opinion allowed, and here's the problem:
18 This device was cleared by the FDA in the 510(k) process. The
19 FDA found that it is substantially equivalent to other
20 devices. Now they've created the inference that it's not
21 substantially equivalent. That is directly contrary to the
22 FDA finding.

23 So by them trying to say that the Obtryx is some type
24 of outlier by virtue of these heat-sealed edges, I believe
25 that -- I think we have two options, she can -- Mr. Love can

—Pence - Direct - Love—

1 stop pursuing this line of testimony, or I'm entitled to bring
2 in the fact that the FDA found that the Obtryx sling is the
3 substantial equivalent of other products on the market.
4 Otherwise, this is extremely prejudicial and unfair.

5 THE COURT: Mr. Love.

6 MR. LOVE: This is the foundation information of her
7 opinion that they should have done testing. They made changes
8 to this product that were unique. Clearance has nothing to do
9 with safety, and he knows this as well as I do. That's why
10 Judge Goodwin always keeps it out. The fact that a product is
11 cleared does not equal safety. But the problem is this
12 product was different than others that came before it but was
13 similar to it, but substantial equivalence doesn't equal
14 safety.

15 Her opinion is that these changes -- in part, is
16 these changes should have been tested before they were
17 available for sale to humans, perfectly in line with her
18 opinion that they should have done human testing.

19 THE COURT: Anything further?

20 MR. ADAMS: Yes. The whole purpose of the 510(k)
21 process is, if the device is substantially equivalent to
22 another device on the marketplace, as determined by the FDA,
23 then the product is cleared. That -- it's undisputed that
24 finding was made. So for the expert and Mr. Love to now come
25 in and say this wasn't equivalent to the other devices is

—Pence - Direct - Love—

1 extremely prejudicial. If -- I have to be allowed to bring up
2 the fact that the FDA found it equivalent. If they didn't,
3 they would have ordered tested.

4 THE COURT: Wait until he's done and go ahead.

5 MR. LOVE: Sure, my apologies.

6 It's factual they made a design change. Clearance
7 doesn't mean safe. That's why -- that's why Goodwin keeps it
8 out.

9 THE COURT: Judge Goodwin, he means.

10 MR. LOVE: I'm sorry. Judge Goodwin. 510(k) has
11 nothing to do with this. It's factual that they made a design
12 change. Nobody is going to dispute that. Her opinion is that
13 design change should have been tested and it wasn't.

14 THE COURT: Okay. Based on my understanding of where
15 she's going, Mr. Adams, I'm going to overrule your objection.
16 I preserve the objection and the exception to testimony, and
17 the judge has, in fact, made the distinction with respect to
18 safety, and he's keeping out the FDA approval. And so, again,
19 if there's other things you hear you want to make objections,
20 but, based on her testimony, I will overrule the objection,
21 preserving the defendant's objection, the exception.

22 MR. ADAMS: Understood.

23 (Sidebar concluded.)

24 BY MR. LOVE:

25 Q. Okay. Are you ready to proceed?

—Pence - Direct - Love—

1 A. I am.

2 Q. Okay. So you explained the design change itself and the
3 ideas behind the design change. Describe for the jury the
4 types of human testing that Boston Scientific performed with
5 respect to this design change.

6 A. It did not perform any human testing.

7 Q. Did they perform any human testing on the heat sealing
8 issue to ensure that it actually did work as they hoped?

9 A. No. They did not.

10 Q. Okay. Were there any randomized controlled trials
11 conducted on the Obtryx sling prior to the time it was made
12 available for sale to humans?

13 A. No.

14 Q. Was it scientifically feasible at this time in 2002 and
15 2003 or 2004 to do a randomized controlled trial to assess the
16 safetiness of this product?

17 A. Absolutely.

18 Q. Okay. Well, let's talk about some other testing. You
19 mentioned that they did do some testing. And I think we
20 talked about some animal testing. Was there an animal test
21 done with respect to the polypropylene?

22 A. There was one animal test done, yes.

23 Q. Okay. Is that the Badylak study?

24 A. That's correct.

25 Q. It's not called the Badylak study, but, again, that's the

—Pence - Direct - Love—

1 author's name?

2 A. That's correct, Dr. Badylak.

3 MR. LOVE: Your Honor, I'd like to publish Exhibit
4 877 for the jury.

5 THE COURT: All right.

6 (The document was published to the jury.)

7 MR. LOVE: Do I wait for an objection, if any?

8 MR. ADAMS: No objection, and the document can be
9 admitted. It's fine with me.

10 THE COURT: All right. Exhibit 877 will be admitted
11 into evidence without objection.

12 Mr. Adams, I apologize to you. I thought that he was
13 making reference to the last exhibit when I told him it was
14 okay to publish it. It has been admitted. It can be
15 published at this point.

16 MR. LOVE: Okay, thank you, ma'am, Your Honor.

17 (PLAINTIFF EXHIBIT P-877 WAS RECEIVED IN EVIDENCE.)

18 (The document was published to the jury.)

19 BY MR. LOVE:

20 Q. Badylak study, something you reviewed in performing your
21 investigation into this case?

22 A. Yes, I did.

23 Q. Okay. Perfect. And let's just kind of walk through it.
24 This will be the first time that the jury has actually seen
25 this. It looks like it's a Boston Scientific animal study?

—Pence - Direct - Love—

1 A. That's correct. It was done under contract at Purdue
2 University for Boston Scientific.

3 Q. Okay. What's the name of the study, for the jury's
4 benefit? They may not able to see that.

5 A. Comparison of tissue ingrowth and histology using
6 synthetic meshes in a chronic rabbit subcutaneous implantation
7 model.

8 Q. Okay. So this is a rabbit study?

9 A. That's correct.

10 Q. Okay. And it's done, it looks like the director of that
11 study is a gentleman by the named of Stephen Badylak, or
12 Dr. Stephen Badylak. Are you familiar with Dr. Badylak?

13 A. I don't know him personally. I'm familiar with him
14 through his testing.

15 Q. Okay. And this was done, it looks like, January, 2003,
16 so about a year and a half before they began selling this
17 product?

18 A. That's correct.

19 Q. Okay. Dr. Badylak, is he an expert in this case for
20 Boston Scientific?

21 A. That's my understanding, he is, yes.

22 Q. The jury will get to meet him in a week or so then, good.

23 All right. Let's talk about this particular study.

24 Let me see if I can work this. Perfect. I just want to run
25 through this, and then I've got a series of questions

—Pence - Direct - Love—

1 before -- just to kind of see where we're at with respect to
2 this study. It says --

3 MR. ADAMS: Excuse me, Mr. Love, can you tell me
4 which page?

5 MR. LOVE: I'm sorry. I apologize. I think it is
6 the next page, the second page, 491.

7 BY MR. LOVE:

8 Q. All right. It says, "This chronic rabbit implantation
9 experiment was performed to compare the tissue response to
10 implantation of three different kinds of synthetic mesh,
11 Control, Pinnacle Sharp and Pinnacle Melted Cut, at two, six,
12 and 12 weeks." And then it looks like it says, "The rabbits
13 received three subcutaneous abdominal wall implants," and then
14 the overview talks about, "There were 36 adult male and female
15 rabbits that were randomly divided."

16 So I just -- I kind of want to summarize. First of
17 all, this was a study in rabbits?

18 A. That's correct.

19 Q. All right. Where did they put the mesh product in these
20 rabbits?

21 A. In the abdominal wall.

22 Q. Where does it go in the human?

23 A. In the -- underneath the urethra, transvaginally,
24 underneath the urethra --

25 Q. So the Obtryx sling --

—Pence - Direct - Love—

1 A. -- for the Obtryx sling.

2 Q. I'm sorry. My apologies. The Obtryx sling is not
3 implanted in the abdominal wall?

4 A. That's correct, it is not.

5 Q. Okay. And it looks like -- how long was this study?

6 A. It was a total of 12 weeks.

7 Q. Okay. Is that a long-term study from your perspective?

8 A. For -- it's titled a chronic study. It is, -- in my
9 view, based on my experience, I would not consider this
10 chronic. It would need to be in the rabbit model at least six
11 months, if not nine months, long to be considered a chronic
12 study.

13 Q. Okay. Now, what does a 12-week study in male rabbits
14 tell us about the long-term complications faced by females?

15 A. It doesn't. It gives us -- it gives us some information
16 about what may be seen in humans over a period of time. So,
17 again, what it really told us here is that more testing was
18 needed based on the outcome of this study.

19 Q. And what was the outcome of this study?

20 A. The outcome of the study was and the reason they have
21 these 36 rabbits, they divided them into three groups of 12,
22 and they sacrificed the animals at two weeks, six weeks and 12
23 weeks. And they looked at the tissue response at those
24 various time periods to -- and basically, what they saw was a
25 typical inflammatory response to a foreign body in the rabbit.

—Pence - Direct - Love—

1 And at 12 weeks, they saw still a persistent
2 inflammatory reaction ongoing at 12 weeks, but they stopped
3 the study there. So they didn't continue it on to see if it
4 completely dissipated. They -- it was highest at two weeks,
5 and then it changed over time and was reduced at 12 weeks, but
6 it was still persistent.

7 Q. Okay. As a clinician, what does this persistent
8 inflammatory response tell you needs to be done next?

9 MR. ADAMS: Your Honor, may we approach?

10 THE COURT: Yes, sir.

11 (The following occurred at sidebar.)

12 MR. ADAMS: This is outside the scope of her report,
13 and it's also outside the scope of her expertise. She said in
14 her report that Boston Scientific only did animal studies.
15 She did not go into the details and criticize the animal
16 studies, which she has now done. She is not a material
17 science expert which is what Dr. Badylak is.

18 So, one, this is outside her expertise. Two, it's a
19 non-disclosed opinion. I should have objected probably two
20 questions earlier.

21 MR. LOVE: She's an expert in preclinical studies and
22 designs. This is right in her expertise. Second, this is
23 foundation for her opinion that the Badylak study -- she's not
24 criticizing it. She's saying it had findings that indicated
25 to a clinician like her that additional tests should be done.

—Pence - Direct - Love—

1 Her opinion is they failed to do those proper additional
2 tests.

3 THE COURT: She needs to get to her opinion. She has
4 stated here with respect to this opinion, when you ask her,
5 which I find is a question asking for the very type of opinion
6 that he's talking about, you ask her, what does a 12-week
7 study in male rabbits tell us about how this device would work
8 in females? And her answer was, it tells us nothing. That
9 is, in fact, a criticism of the study. So it can be
10 interpreted in that way.

11 MR. LOVE: Okay.

12 THE COURT: I think that she -- I'm going to limit
13 her to the opinions that are outlined in her report, those
14 which have not been excluded by Judge Goodwin, and if she did
15 not give opinions criticizing this animal study, I am going to
16 exclude those opinions.

17 MR. LOVE: Okay. This is cited in her opinions to
18 her report and is as a precursor, I will be happy to move on.

19 THE COURT: I think because she is testifying,
20 Mr. Love, about testing and she is going to criticize the
21 testing which is valid based on the opinion that she gave,
22 she's certainly in a position to testify that that 12-week
23 study told her that more testing was needed.

24 MR. LOVE: Okay.

25 THE COURT: But she went somewhat further than that

—Pence - Direct - Love—

1 when she said that it would --

2 MR. LOVE: Okay.

3 THE COURT: I think that is at least an implied
4 criticism of testing.

5 MR. LOVE: Okay.

6 THE COURT: To that extent, I will preserve the
7 objection -- I sustain your objection and preserve an
8 objection exception for you, Mr. Love.

9 MR. LOVE: Thank you.

10 (Sidebar concluded.)

11 BY MR. LOVE:

12 Q. Are you ready?

13 A. Ready.

14 Q. Let's kind of wrap up the Badylak study. The conclusion
15 was, you identified, I think, persistent inflammation. What
16 does that tell you as a clinician?

17 A. That tells me that more testing needed to be done, a
18 longer period of testing in animals, but also that that could
19 also mean that in humans, there may be a mild and persistent
20 chronic inflammation that occurs with implantation of the
21 mesh.

22 MR. ADAMS: Objection, Your Honor.

23 THE COURT: Objection to that portion of the response
24 is sustained, counsel.

25 MR. LOVE: Perfect.

—Pence - Direct - Love—

1 MR. ADAMS: And, Your Honor, I move that it be
2 stricken.

3 THE COURT: I will strike it from the record. The
4 latter part of her answer, Mr. Love.

5 MR. LOVE: Thank you, Your Honor.

6 BY MR. LOVE:

7 Q. Does the Badylak study support your opinion that
8 additional human testing should have been done?

9 A. Yes, it does.

10 Q. Okay. Let's talk about the Material Safety Data Sheet.
11 Are you familiar with it?

12 A. Yes, I am.

13 Q. Okay. Now, the jury has seen, has heard from a Charles
14 Smith, and he's talked about it, so I don't want to go over or
15 repeat it.

16 But why is it -- just briefly, why is the Material
17 Safety Data Sheet, as it pertains to polypropylene, relevant
18 to your opinion in this case about testing?

19 A. It is important to my opinion because of the medical
20 caution statement that is on that Material Safety Data Sheet.

21 Q. Let's back up a little bit and lay a little bit of
22 foundation.

23 Do manufacturers of medical devices receive parts or
24 substances from suppliers when developing new products? Is
25 that unusual?

—Pence - Direct - Love—

1 A. No, it's not unusual.

2 Q. Okay. How do they -- and they then incorporate those
3 products into their device; is that fair?

4 A. The components, they incorporate into their devices, yes,
5 they --

6 Q. Okay. And is it standard in the industry for those
7 suppliers to provide safety information regarding component
8 parts where appropriate?

9 A. That's correct.

10 Q. Have you seen that over your 40-plus years in working in
11 the medical device industry?

12 A. Yes, I have.

13 Q. Okay. And where is this type of information typically
14 maintained by the medical device company if they receive such
15 information?

16 A. It's maintained in the device records for development of
17 the device.

18 Q. Okay. Let's talk about the Obtryx sling. Are there
19 component parts for this device that were received by outside
20 suppliers?

21 A. Yes.

22 Q. All right. And --

23 A. Received from outside suppliers, yes.

24 Q. What component part are we specifically talking about
25 when we're talking about the polypropylene mesh?

—Pence - Direct - Love—

1 A. The polypropylene resin.

2 Q. And who were they -- who was Boston Scientific receiving
3 this particular resin from during the relevant time period
4 prior to launch?

5 A. From a company called Phillips Sumika which was a joint
6 venture of Chevron Phillips with another company, Sumitomo
7 Chemical, if I recall correctly was the name of the other
8 company.

9 Q. Okay. Fair enough.

10 MR. LOVE: Your Honor, at this time I would like to
11 move for the admission of Exhibit 1004, which I believe would
12 be the fourth tab on your notebook, as well as yours,
13 Mr. Adams.

14 THE COURT: Objection, counsel?

15 MR. ADAMS: And, Your Honor, subject to our prior
16 objections.

17 THE COURT: All right. I overruled or reaffirmed the
18 objections that you have previously made, the rulings to those
19 objections, and admit Exhibit 1004, preserving the defendant's
20 objection and exception.

21 (DEFENDANT EXHIBIT 1004 WAS RECEIVED IN EVIDENCE.)

22 (The document was published to the jury.)

23 BY MR. LOVE:

24 Q. And with respect to Exhibit 1004, have you had an
25 opportunity to review the January 1st, 2004, MSDS provided by

—Pence - Direct - Love—

1 Chevron Phillips to Boston Scientific?

2 A. Yes, I have.

3 Q. And is it relevant to your opinions in this case?

4 A. Yes, it is.

5 Q. Okay. And let's take a look at it. And this is
6 something that's not unfamiliar to you or the jury at this
7 point, so I'll kind of just get to the point here.

8 Okay. The jury has seen the medical application
9 caution here. Why is this important to you as a clinician who
10 helps companies prepare studies to launch new medical devices?

11 A. This is important because this says that the raw material
12 is not intended for use in permanent implantation in the human
13 body or permanent contact with body fluids or tissues. And
14 what that means to me is that there has been no testing to
15 determine its appropriateness or its fitness for permanent
16 implantation.

17 Q. Okay. And what does that tell you needs to happen as a
18 clinician?

19 A. More testing.

20 Q. Okay. Human testing?

21 A. Appropriate testing.

22 Q. Human testing?

23 A. Human testing, that's correct.

24 Q. Okay.

25 A. Animal testing first and then human testing.

—Pence - Direct - Love—

1 Q. Let's talk about what happened after Boston Scientific
2 received this. That's January 28, 2004, correct?

3 A. That's correct.

4 Q. All right. And the product began to be made available
5 for sale to humans in August, 2004, right?

6 A. That's correct.

7 Q. So we're looking about seven or eight months or so there,
8 right.

9 A. That's correct.

10 Q. Okay. After receiving this in January, what specific
11 study did Boston Scientific initiate to ensure that this
12 product was safe?

13 A. Boston Scientific did not initiate a study.

14 Q. Did they halt production of the Obtryx sling until
15 studies were completed?

16 A. No, they did not.

17 Q. Did they do a press release saying we have received new
18 information?

19 A. No.

20 Q. Okay. Now, you've actually looked at a lot of documents,
21 I assume?

22 A. I have.

23 Q. Okay. Do you feel like you've done a pretty thorough
24 search?

25 A. I've done a very thorough search, that's correct.

—Pence - Direct - Love—

1 Q. Okay. Was this the first time that any chemical company
2 was telling Boston Scientific not to use it for permanent
3 implantation, that you're aware of?

4 A. Yes, that's correct.

5 Q. What did they do?

6 A. They did nothing. They kept selling -- well, they
7 marketed the product in August of 2004 without doing any
8 testing to determine the appropriateness of the polypropylene
9 for permanent implantation in the -- as the Obtryx Sling.

10 Q. Now, if a company like Boston Scientific does not study
11 its products to ensure its safe in humans, what are the
12 potential consequences?

13 A. Safety risks, not -- that it may not work, as well, may
14 not be effective. But, most importantly, that there may be
15 safety problems with it --

16 Q. Okay.

17 A. -- once it is used in humans.

18 Q. Now, I heard Mr. Adams in opening statement saying that
19 this polypropylene stuff that we're complaining about has been
20 used in different body parts for 55 years. Have you heard
21 that before?

22 A. Yes, I have.

23 Q. Okay. Can a product that is safely used in one part of
24 the body automatically be assumed to be safe in all parts of
25 the body?

—Pence - Direct - Love—

1 A. No, it cannot.

2 Q. Okay. Why not?

3 A. Well, the ProteGen sling is a perfect example. The
4 ProteGen sling was previously used and was used in vascular
5 grafts as a product called Hemashield, and once it was used in
6 the vaginal application for which Boston Scientific marketed
7 it --

8 MR. ADAMS: Objection, Your Honor. This is, again,
9 outside the scope and lack of foundation.

10 THE COURT: Response, counsel?

11 MR. LOVE: Your Honor, it's one of the things that we
12 need to distinguish, that I presented in opening and what's
13 cited in her report, is that studies that were conducted and
14 completed on other products can't establish that this product
15 is safe, and she's just making that clarification as a
16 clinician that you need to study your own products.

17 MR. ADAMS: May we approach, Your Honor?

18 THE COURT: All right.

19 (The following occurred at sidebar.)

20 THE COURT: There was an objection to the question
21 about whether or not one could assume that a device that's
22 been used in other parts of the body is safe for all portions.
23 There was an objection, counsel. Next question --

24 MR. ADAMS: Right. And I appreciate that, Your
25 Honor. My objection is he's far beyond the scope of the

—Pence - Direct - Love—

1 opinion allowed by Judge Goodwin. The opinion allowed by
2 Judge Goodwin was they should have done premarket clinical
3 testing. She's already stated that opinion and the basis.
4 Now for her to start talking about studies and whether those
5 studies justify the use of polypropylene is outside the scope.

6 THE COURT: Mr. Love?

7 MR. LOVE: That was my fault because I did miss that.

8 Her opinion is that part of her investigation, she
9 reviewed all of the available literature and she says you have
10 to. You have to look at studies that are done on other
11 products because they will give you insight into what's
12 appropriate for your product. All I'm establishing is she's
13 saying that looking at other products exclusively doesn't get
14 you the appropriate testing in this product. And so her
15 opinion is perfectly consistent and contained within her
16 report. She's saying look at the universe, but only looking
17 at studies on other products and not this one isn't sufficient
18 as a company.

19 THE COURT: It would seem to me that she has made
20 that statement.

21 MR. LOVE: Yes.

22 MR. ADAMS: Okay.

23 THE COURT: And so I don't know if you --

24 MR. LOVE: I'll move on.

25 THE COURT: All right.

—Pence - Direct - Love—

1 MR. ADAMS: Well, I don't want to keep interrupting
2 either. In the notebook are reports, actual studies that
3 postdate the launch of the Obtryx. There is no reason why she
4 should be able to go into studies that postdate the launch.
5 The sole reason is that --

6 MR. LOVE: I haven't done that.

7 MR. ADAMS: Okay.

8 THE COURT: And that, therefore, is consistent with
9 what the judge has ruled that she's not permitted to do that.

10 MR. LOVE: Okay.

11 MR. ADAMS: Okay.

12 THE COURT: Anything further either of you want to
13 place on the record?

14 MR. ADAMS: No, Your Honor.

15 MR. LOVE: No.

16 MR. ADAMS: Thank you.

17 (Sidebar concluded.)

18 BY MR. LOVE:

19 Q. Okay. Are you ready?

20 A. I'm ready.

21 Q. I'm trying to figure out -- I'm trying to wind this down,
22 if I can.

23 Mid-urethral slings, the Obtryx is a mid-urethral
24 sling?

25 A. That's correct, it is.

—Pence - Direct - Love—

1 Q. There have been a number of studies done on mid-urethral
2 slings, right?

3 A. That's correct.

4 Q. There have been -- half dozen or a dozen or whatever on
5 Obtryx, but a whole bunch on other types of mid-urethral
6 slings; fair?

7 A. That's correct.

8 Q. All right. Is it okay for a company like Boston
9 Scientific to rely upon studies done on other products to
10 establish that the Obtryx Sling is safe?

11 MR. ADAMS: Objection, Your Honor, outside the scope.

12 THE COURT: That question has been asked and answered
13 prior to you all coming to the bench.

14 MR. ADAMS: Plus cumulative. I'm sorry.

15 THE COURT: That objection is sustained.

16 MR. LOVE: Okay. Fair enough.

17 BY MR. LOVE:

18 Q. At the end of the day, I guess just to close this out,
19 what is your opinion as to what the appropriate testing Boston
20 Scientific should have done prior to selling this product to
21 humans?

22 MR. ADAMS: Objection, Your Honor. This is
23 cumulative.

24 MR. LOVE: Well, I'm asking for specific times of
25 studies.

—Pence - Cross - Adams—

1 THE COURT: I will overrule it at this point,
2 counsel, until I can see where this is going. If you feel the
3 need to interject other objections, I'll address them.

4 Go ahead, Mr. Love.

5 THE WITNESS: Boston Scientific should have done
6 additional preclinical testing and then human testing,
7 particularly a randomized controlled clinical trial of an
8 appropriate design prior to marketing this product --

9 Q. That's --

10 A. -- for permanent implantation. Sorry.

11 Q. I appreciate your time today.

12 A. Thank you.

13 MR. LOVE: Can I get my Obtryx Sling back from you?

14 THE WITNESS: Thank you.

15 THE COURT: Cross examination.

16 MR. ADAMS: Yes, Your Honor.

17 (CROSS EXAMINATION OF PEGGY PENCE BY MR. ADAMS:)

18 Q. Good afternoon, Dr. Pence.

19 A. Good afternoon.

20 Q. We have met before, haven't we?

21 A. We have.

22 Q. I have some follow-up questions for you. And if we
23 could, could we put those background slides up that you
24 started with?

25 In your testimony with Mr. Love, you were talking about

—Pence - Cross - Adams—

1 your background and work that you do in litigation. Do you
2 recall that?

3 A. I do.

4 Q. And you, in fact, are being paid \$500 an hour for your
5 work in this case, correct?

6 A. For my time, that's correct.

7 Q. And you -- you first began consulting on Boston
8 Scientific litigation about a year and a half ago, two years
9 ago; is that correct?

10 A. It would have been sometime in 2013, that's correct.

11 Q. All right. And at least as of August of 2014, you had
12 billed over \$300,000 on Boston Scientific matters, correct?

13 A. That's correct.

14 Q. And the amount that you've billed since August is now
15 much higher, correct?

16 A. I haven't billed it yet but there are certainly more
17 hours that have been --

18 Q. You put on --

19 A. -- extended.

20 Q. Okay. You are now up over \$500,000, correct?

21 A. I haven't totaled it. I anticipate that my own time that
22 I've probably spent in total about 500 hours at this point in
23 time on the Obtryx, the Obtryx Sling, Pinnacle Sling, other
24 Boston Scientific products.

25 Q. And besides you billing out \$500 an hour, you also bill

—Pence - Cross - Adams—

1 out other individuals at your company at \$90 an hour, \$150 an
2 hour, and \$350 an hour, correct?

3 A. That is correct.

4 Q. And now, in this case, I want to go back. With respect
5 to these slides, you had -- when you were talking with
6 Mr. Love, you were talking about the consulting work that you
7 do with other -- these other companies. You mentioned the
8 three different areas: Pharma, bio, and medical, correct?

9 A. That's correct, medical device.

10 Q. And the area of litigation support, you had mentioned to
11 Mr. Love that you got into that about five years ago, correct?

12 A. Five to six years ago, that's correct.

13 Q. And your income from litigation support has steadily
14 increased since you got into litigation five years ago,
15 correct?

16 A. That would be correct. It's --

17 Q. And, in fact, if we go back, when you got in in 2008,
18 your litigation income was about five percent of your
19 company's revenue, correct?

20 A. I would have to -- for 2008, I really was only contacted
21 towards the end of 2008 and really only began work in 2009.

22 Q. Okay. Do you disagree with that? I've got a transcript
23 I could show you that your litigation income, you estimated,
24 was about five percent of your revenue in 2008.

25 A. It would have been no more than that, that's correct.

—Pence - Cross - Adams—

1 Q. And then in 2011, litigation income comprised 30 to 50
2 percent of your company's revenue, correct?

3 A. That sounds about right. I would have to look back at
4 the actual percentages several years ago to confirm that.
5 That sounds about right.

6 Q. And recently, in 2014, you've estimated that income from
7 litigation is now 50 to 60 percent of the revenue of your
8 company, correct?

9 A. Yes. It's variable, depending on whether I'm teaching or
10 what -- what stage of litigation the projects I'm working on
11 are.

12 Q. Okay. So if we're looking at this chart, and we were
13 trying to figure out what percentage of revenue you make out
14 of testifying in litigation like this, if we draw a line right
15 here, as far as the revenue, 50 to 60 percent comes from your
16 work in litigation support, correct?

17 A. That would be correct. And it's variable.

18 Q. And -- now, you've testified in other cases before,
19 correct?

20 A. Yes, I have.

21 Q. And you've given testimony against other medical device
22 companies, correct?

23 A. Yes, I have.

24 Q. And isn't it true that you have never given testimony on
25 behalf of a medical device company in either a deposition or

—Pence - Cross - Adams—

1 at trial like we're here now, correct?

2 A. If you're limiting it to a deposition or a trial, that's
3 correct.

4 Q. Again, my question is: Isn't it true you have never
5 given testimony in a deposition or a trial on behalf of a
6 medical device company? Correct?

7 A. As I said, if you're limiting to that, that is correct.

8 Q. And with respect to the Obtryx and polypropylene, you've
9 talked a lot about that. Isn't it true that before your
10 assignment in this litigation, you had never done any research
11 into polypropylene?

12 A. That's correct.

13 Q. And you had not done research, testing, and evaluation of
14 polypropylene products before you were hired by the plaintiffs
15 in this litigation, correct?

16 A. That's correct.

17 Q. And since -- and let's talk about the mechanics.

18 When you were hired to start learning about
19 polypropylene, you were essentially engaged by one of the
20 plaintiffs' firms at a rate of \$500 an hour, correct?

21 A. For my time, that's correct.

22 Q. And then what you did is is that you reviewed a variety
23 of documents that came from Boston Scientific, correct?

24 A. That were produced by Boston Scientific, as well as I
25 mentioned, I did my own independent research as well, my own

—Pence - Cross - Adams—

1 reviews of the scientific and medical literature, other types
2 of relevant documents.

3 Q. And let's just talk about the information from Boston
4 Scientific. You know that Boston Scientific produced
5 documents in this case to plaintiffs' counsel, correct?

6 A. That's correct.

7 Q. And you know that you were then supplied or provided a
8 percentage of those documents from plaintiffs' counsel,
9 correct?

10 A. I wouldn't -- I can't agree with your question just as
11 you've asked it because, yes, I was provided documents, but I
12 also was given access to other documents and requested a
13 number of documents. As a scientist, as I review information,
14 it raises questions, then there are other documents that I
15 need to see in order to answer my questions to do an
16 appropriate investigation. So I repeatedly asked for
17 documents. So I did not -- if you're suggesting that I only
18 reviewed what was provided to me and nothing beyond that, that
19 is inaccurate.

20 Q. All right. No, but your source of information about
21 documents from Boston Scientific would have to come from
22 plaintiffs' counsel; agreed?

23 A. Yes, as provided by Boston Scientific.

24 Q. And when we talk about -- you had given a number of
25 opinions today on -- for example, the testing of -- done by

—Pence - Cross - Adams—

1 Dr. Badylak. Now, you know Dr. Badylak is a biomaterials
2 expert, correct?

3 A. He's in the Department of Biomechanical Engineering.

4 Q. At what university?

5 A. Perdue University.

6 Q. And do you know how many published papers Dr. Badylak has
7 in the area of materials science?

8 A. I haven't counted them.

9 Q. Do you have one?

10 A. No, I don't.

11 Q. And you're obviously not a bio- -- you're not a
12 biomedical engineer or a materials science expert, correct?

13 A. No. I have a Ph.D. in toxicology.

14 Q. I realize that, but you're not a biomaterials expert,
15 correct?

16 A. That's correct.

17 Q. And you've never done -- outside of this litigation,
18 you've never been engaged by a company or on your own to
19 research what happens to polypropylene inside the human body,
20 correct?

21 A. Not for polypropylene specifically, that's correct.

22 Q. And, obviously, you've never been involved in the design
23 of any kind of polypropylene mesh product or SUI products,
24 correct?

25 A. That's correct.

—Pence - Cross - Adams—

1 Q. Now, let's talk about the history of polypropylene just
2 for a little bit. Mr. Love brought that up.

3 You know, and Mr. Love brought up, that polypropylene's
4 been used in the body for years, correct?

5 A. Yes, it has.

6 Q. It goes back to the 1950s when -- actually, there was an
7 individual, you cited a report in your -- in your report,
8 there was a study done by a Dr. Usher on the use of Marlex
9 polypropylene mesh in the human body, correct?

10 A. It's -- yes, that's correct.

11 Q. And Marlex is a specific name of a specific type of
12 polypropylene compound, correct?

13 A. It's the polypropylene that's used in the Obtryx Sling,
14 yes.

15 Q. Exactly. The exact same material, the exact same
16 polypropylene compound that Dr. Usher wrote his papers about
17 regarding the use of that compound in the body in the 1950s,
18 is the same compound that Boston Scientific used in the
19 Obtryx, correct?

20 A. Without comparing how his material was processed versus
21 knowing how the current polypropylene resin is processed, I
22 can't say that it was exactly the same.

23 Q. Well, now, ma'am, you've talked a lot about the danger of
24 this Marlex polypropylene. Did you not investigate that issue
25 before you came in here to testify to the jury?

—Pence - Cross - Adams—

1 A. I didn't investigate it compared to Dr. Usher's -- the
2 product that he used back in the 1950s.

3 Q. But you've agreed with me that the compound that is used
4 in the Obtryx and that was used back in the '50s in the Usher
5 studies is the Marlex polypropylene compound, correct?

6 A. I have -- I've not agreed that it's the same product.
7 Over a period of 50 years, there may have been changes in the
8 processing, and without doing that comparison, what the
9 leachables may be from the polypropylene, I can't say if
10 they're identical. They may have the same name but the
11 product may not be the same over a 50-year period.

12 Q. But you're not willing to tell this jury that -- one way
13 or another whether it's the same compound because you haven't
14 done that research, correct?

15 MR. LOVE: Objection, Your Honor. If he's going to
16 cross-examine her on the study, certainly, he can make it
17 available, they can find out if it's the same.

18 MR. ADAMS: I'm just asking her.

19 THE COURT: I'm going to permit her to answer if she
20 can. Go ahead, please.

21 BY MR. ADAMS:

22 Q. Did you do the research to determine whether it's the
23 same compound?

24 A. I didn't because it doesn't matter to me --

25 Q. I'm just asking whether you did it or not.

—Pence - Cross - Adams—

1 A. -- because it's used in the Obtryx, and the important
2 point is that the Obtryx Sling in its current composition
3 needed to be tested to determine if the Obtryx Sling was
4 appropriate for marketing. Boston Scientific is not marketing
5 the Usher product. It's marketing the Obtryx Sling.

6 MR. ADAMS: Your Honor, I move to strike everything
7 after "I didn't."

8 THE COURT: I'm going to overrule that motion,
9 counsel, and I'll address it at the bench at a later time if
10 you all want.

11 MR. ADAMS: Understood.

12 BY MR. ADAMS:

13 Q. Now, let's go back and talk about the use of the
14 particular polypropylene resin by Boston Scientific and Boston
15 Scientific's product. You know that Boston Scientific
16 originally started buying that same polypropylene resin back
17 in 1992, correct?

18 A. I don't recall the year specifically, but, yes, early
19 '90s, to the best of my recollection.

20 Q. All right. And, in fact, let me show you a timeline,
21 you've seen this before, for us to work off of. The timeline
22 that we are looking at, Dr. Pence --

23 MR. ADAMS: Yes. It was the one I used in opening
24 but I'll give you a copy.

25 BY MR. ADAMS:

—Pence - Cross - Adams—

1 Q. Dr. Pence, the timeline that I've handed you will help
2 us -- orient us on the dates. And you've testified and
3 researched the products that use this same Marlex
4 polypropylene, correct?

5 A. Yes.

6 Q. And so if we could put up on the screen the timeline.
7 And this is the same one I used in opening.

8 (The document was published to the jury.)

9 BY MR. ADAMS:

10 Q. Now, the -- and we will get into this MSDS sheet. Just
11 so the jury has a reference, the MSDS sheet that Mr. Love
12 asked you some questions about with the medical application
13 caution, which is Exhibit 1004, that medical application
14 caution first came out on January 28th of 2004, correct?

15 A. That's correct.

16 Q. And prior to January 28th of 2004, Boston Scientific had
17 been buying the exact same Marlex polypropylene resin from
18 Phillips Sumika, correct?

19 A. That's correct.

20 Q. And those purchases go all the way back to 1992 when
21 Boston Scientific was actually selling the Trelex hernia mesh,
22 correct?

23 A. Yes. I believe they began selling it in 1993, to the
24 best of my recollection.

25 Q. Okay. And you know that that exact same compound, not

—Pence - Cross - Adams—

1 only was it used in Trelex starting in 1992, but it was also
2 used in the Advantage sling, the Lynx sling, in 2002, correct?

3 A. Yes, it was.

4 Q. And then we have its use in the Obtryx in -- which was
5 launched on April 14th of 2004, correct?

6 A. That's correct.

7 Q. And then later used in the Solyx, which was launched on
8 August 27th of 2008, correct?

9 A. Yes.

10 Q. And, by the way, both the Advantage, the Lynx, the Obtryx
11 and the Solyx, those are products that are still being sold
12 today, correct?

13 A. That's -- actually, I'm not certain about the Obtryx.
14 According to deposition testimony that I've read -- I'm not
15 sure what deposition testimony that I've read -- it is still
16 on the market, but I was recently checking the website for
17 Boston Scientific and it does not show Obtryx. It shows
18 Obtryx II as one of the five available slings on the market.

19 Q. All right. You don't know one way or another whether
20 Obtryx is still being sold; fair?

21 A. Well, what I'm saying is there is a disconnect between
22 what's on the website that I accessed recently and the most
23 recent deposition testimony to which I have access.

24 Q. You know the Advantage and the Lynx and the Solyx are
25 also being sold, correct?

—Pence - Cross - Adams—

1 A. Yes.

2 Q. All right. Now, and the chemical composition of this
3 polypropylene has remained the same from '92 all the way to
4 the present date, correct?

5 A. I can't speak to the present day because my understanding
6 is that --

7 Q. I will rephrase the question.

8 A. -- Boston Scientific is no longer --

9 THE COURT: Just a second. The court reporter can't
10 take down both of you. Mr. Adams, I'm going to let you ask
11 your question. I want you to listen carefully, Doctor, and
12 answer it. Go ahead, please.

13 MR. ADAMS: And I'll rephrase the question.

14 BY MR. ADAMS:

15 Q. You'll agree with me that the chemical composition of the
16 Marlex polypropylene resin remained the same from the time
17 Boston Scientific purchased it for the Trelex all the way
18 through the time the Obtryx launched in April of 2004,
19 correct?

20 A. The Obtryx actually launched in August of 2004, but,
21 other than that, yes, the answer to your question is yes.

22 Q. And we know that prior to -- again, prior to January of
23 2004, there was never any MSDS medical caution like what we've
24 seen in Exhibit 1004, correct?

25 A. That's correct.

—Pence - Cross - Adams—

1 Q. So the exact same material stayed the same and the only
2 thing that changed was the addition of the medical application
3 caution, correct?

4 A. Would you repeat that question?

5 Q. The material stayed the same; the only difference was the
6 addition of the language of the medical application caution,
7 correct?

8 A. The Marlex mesh sold by the -- Phillips Sumika stayed the
9 same, to the best of my knowledge.

10 Q. All right. And this Material Safety Data Sheet, now, you
11 know that a Material Safety Data Sheet is put out pursuant to
12 OSHA regulations, correct?

13 A. That's correct.

14 Q. And OSHA stands for what?

15 A. Occupational Safety and Hazards --

16 Q. Administration?

17 A. Administration. Thank you.

18 Q. You did pretty well.

19 And, basically, what OSHA does is OSHA's job is to
20 promulgate rules with respect to workers that will handle raw
21 materials like polypropylene pellets, correct?

22 MR. LOVE: Objection.

23 THE WITNESS: For that --

24 THE COURT: I'm sorry.

25 MR. LOVE: Objection to proper foundation.

Pence - Cross - Adams

1 THE COURT: Counsel?

2 MR. ADAMS: I'm asking --

3 THE COURT: Do you understand the objection?

4 MR. ADAMS: I don't.

5 THE COURT: Mr. Love? Improper foundation? I assume
6 you all want to come to the bench.

7 (The following occurred at sidebar.)

8 MR. LOVE: He's laying a foundation about what OSHA
9 requires, without any foundation, without asking if she's
10 familiar with them. I mean, he's offering expert testimony as
11 a lawyer.

12 MR. ADAMS: I'm just asking if this is done pursuant
13 to OSHA regulations, which she's answered OSHA is responsible
14 for protecting workers. I'm not going to go into that the FDA
15 is responsible because I can't do it, but I can definitely
16 show that OSHA promulgates rules for MSDSs.

17 THE COURT: I think Mr. Love's objection, if I
18 understand, is that there has been no real foundation laid as
19 to her knowledge about that. And I think if you lay that,
20 your objection will be moot, and if I don't understand it,
21 Mr. Love, I want you to let me know.

22 MR. LOVE: I think that's exactly right. What he's
23 trying to suggest is those OSHA regs are for protection of
24 workers and that's not the case. That's part of the reason
25 they exist. So if he wants to lay the foundation and say what

—Pence - Cross - Adams—

1 the purpose of the OSHA regs are, to protect end users which
2 could be workers and could be medical device companies, that's
3 appropriate.

4 THE COURT: Well, more importantly, neither of you
5 testify. Now, she has the requisite knowledge to answer that
6 question so let's go there. I sustain the objection to the
7 lack of foundation, preserving the objection and exception.

8 MR. ADAMS: I'll go back and try it again.

9 (Sidebar concluded.)

10 BY MR. ADAMS:

11 Q. Dr. Pence, let me go back to where I was.

12 Did you review the OSHA regulations concerning what
13 OSHA specifies must be contained within a Material Safety Data
14 Sheet as part of your work in this case?

15 A. Yes, I have.

16 Q. All right. And you know that OSHA has specific
17 regulations concerning what must be set forth in the various
18 sections of a Material Safety Data Sheet, correct?

19 A. Yes.

20 Q. And the hazards to humans must be set forth in Section 3
21 of document 1004 which is called the Hazards Indication
22 Section, correct?

23 A. If you'd like -- I don't recall the section by heart. If
24 you'd like to show it to me, I would be happy to look at it.

25 Q. Certainly.

—Pence - Cross - Adams—

1 A. But I know that it does specify that in a particular
2 section, yes.

3 Q. And if we have it -- you can put your document up on the
4 screen. This is 1004. You'll need to switch over.

5 And if we could turn to the next page within this
6 document. Do you not have the full document loaded?

7 MR. LOVE: I have it handy if you want it.

8 MR. ADAMS: That would be fine. Do you have an extra
9 copy? Thank you.

10 BY MR. ADAMS:

11 Q. Dr. Pence, the jury will have this in evidence later and
12 I don't want to belabor the issue, but I'm handing you Exhibit
13 1004, correct?

14 A. Yes.

15 Q. And 1004 is the Material Safety Data Sheet that contains
16 the medical application caution, correct?

17 A. Yes, it is.

18 Q. And you know that under the OSHA regulations, under
19 Section 3 of that document, you must identify hazards
20 associated with the product, correct?

21 A. Correct.

22 Q. And under the hazards identification, there does not
23 contain any information regarding that -- the statement that
24 this product should not be used in medical applications or
25 implanted in the human body, correct?

—Pence - Cross - Adams—

1 A. Not in that section, that's correct.

2 Q. And with respect to this Material Safety Data Sheet, you
3 are aware that the corporate representative of Phillips Sumika
4 has been deposed in this matter, correct?

5 A. I am. I've read the deposition.

6 Q. And you, as part of your work, not only did you look at
7 documents, but you looked and read deposition testimony,
8 correct?

9 A. That's correct.

10 Q. And you understand that that deposition was a -- what's
11 called a corporate designee deposition under Rule 30(b)(6),
12 correct?

13 A. Yes, I do understand that.

14 Q. And under that rule, that company was commanded to bring
15 to the deposition any scientific studies or data that supports
16 the language in that medical application caution, correct?

17 A. Yes.

18 Q. And you know that Phillips Sumika, when they testified in
19 that deposition through an individual named Frank "Z" -- he's
20 got a hard name.

21 A. Yes, he does.

22 Q. They produced no scientific studies and no other studies
23 to establish that they had a basis for adding that medical
24 application caution, correct?

25 A. To the best of my recollection, the deposition testimony

—Pence - Cross - Adams—

1 was that he did not know the reason studies were not done but
2 that the fact that studies were not done did not mean that
3 there was not a scientific basis.

4 Q. Well, ma'am, and the jury will see this. The individual
5 was not aware of any scientific basis to support that
6 statement, correct?

7 A. To the best of my knowledge, that is correct.

8 Q. And the individual and the company who was commanded to
9 produce any scientific studies or any basis for that statement
10 produced zero documents at that deposition, correct?

11 A. To the best of my recollection, that's correct. But if
12 you have his deposition, I would be happy to take a look at it
13 and refresh my memory because there was some very specific
14 questioning along those lines --

15 Q. And the jury will see that.

16 A. -- and he was very careful to respond, as I mentioned,
17 that he really didn't know the reason for that statement.

18 Q. And, ma'am, you know that attached to the deposition,
19 there were no studies or documents to support the statement,
20 correct?

21 A. That were provided at that deposition.

22 Q. All right. And --

23 A. That's correct.

24 Q. In fact, from your review of information from Boston
25 Scientific --

—Pence - Cross - Adams—

1 MR. ADAMS: Can we put our timeline back up? We need
2 to change the box.

3 BY MR. ADAMS:

4 Q. Okay. From your review of the Boston Scientific
5 information, after Phillips Sumika included this language in
6 the MSDS that had never been there before, you know that
7 people at Boston Scientific such as Doreen Rao investigated as
8 to why that language was included, correct?

9 A. I know she was -- yes, she was deposed about that, that's
10 correct.

11 Q. And, in fact, Doreen Rao has testified that she learned
12 from Phillips Sumika that there was no scientific basis for
13 the language and it was simply added as legal language,
14 correct?

15 A. To the best of my recollection, there is also
16 testimony -- if you have her deposition, I would be happy to
17 refresh my memory -- but, to the best of my recollection,
18 there is also testimony from Doreen Rao that that statement
19 could not be taken as not having meaning.

20 Q. But you know that she testified that one of the reasons
21 she was provided by Phillips Sumika for the inclusion of the
22 language was for legal reasons, correct?

23 A. I don't recall that specific testimony. If you have it
24 in front of you and would like to show it to me, I will be
25 happy to refresh my memory.

—Pence - Cross - Adams—

1 Q. The jury will hear from Ms. Rao on that issue.

2 Let's talk about -- it's a good sign when I'm turning
3 all these pages, Dr. Pence.

4 Let's talk about your testimony regarding premarket
5 clinical studies, and you gave some testimony regarding the
6 detanged edges on the Obtryx and the Advantage mesh, correct?

7 A. Yes.

8 Q. And you, ma'am, know that that product, the product which
9 is the Obtryx and the Advantage, those have been found to be
10 substantially equivalent to other meshes that were on the
11 market --

12 MR. LOVE: Objection, Your Honor. May we approach?

13 THE COURT: Yes, sir.

14 (The following occurred at sidebar.)

15 THE COURT: Okay, Mr. Love.

16 MR. LOVE: This has specifically been excluded. He's
17 just carefully -- he's not using clearance, he's using
18 substantial equivalence to suggest that it was being cleared
19 and/or approved and safe. This is what 510(k) process is. It
20 is substantial equivalence. Judge Goodwin has consistently
21 said this is off base.

22 MR. ADAMS: He said that I can't refer to the FDA but
23 I'm not referring to the FDA. I'm entitled to say that they
24 have found to be substantially equivalent to other products.

25 MR. LOVE: That's not --

—Pence - Cross - Adams—

1 THE COURT: Be found by who, Mr. Adams?

2 MR. ADAMS: I can simply say a regulatory body.

3 MR. LOVE: This is the whole reason why he kept it
4 out. Judge Goodwin has said substantial equivalence doesn't
5 equal safety. The 510(k) process doesn't do that.

6 MR. ADAMS: Okay. The problem that I have is she
7 created the inference that our mesh is somehow different than
8 the other meshes. That's been found to be substantially
9 equivalent by the government. I can rephrase it and just
10 use -- I didn't even say what entity but I can just say
11 regulatory body.

12 THE COURT: Give me your question, Mr. Adams.

13 MR. ADAMS: You would agree that the Obtryx has been
14 found to be substantially equivalent to other meshes on the
15 market, correct?

16 MR. LOVE: This is back-dooring the FDA approval
17 process.

18 THE COURT: All right. I'm going to overrule the
19 objection. There is nothing in his question that would
20 indicate that it was substantially similar to either such
21 devices on the market and that it's been proved by anyone, or
22 including the FDA, that it is substantially similar to other
23 devices that are currently on the market. Because of the
24 phrasing of the question, I don't think it it's violative of
25 the order. It's violative to you because you know what the

—Pence - Cross - Adams—

1 arguments were. The jury has no idea about that. So, again,
2 I don't think it brings any -- any proof about regulatory
3 agencies.

4 MR. LOVE: Okay.

5 THE COURT: I murdered that statement.

6 My point is this: As the question has been phrased
7 by Mr. Adams, I do not believe it brings into play any
8 approval or non-approval by any regulatory agency. It does to
9 the lawyers because they know what the pretrial arguments
10 were, but to the jury it doesn't, and so I don't think it runs
11 afoul of the Court's order.

12 MR. LOVE: Can I ask you to the extent -- I just want
13 to make sure we're clear. There is no second question saying
14 by whom it wasn't found to be substantially equivalent?

15 THE COURT: Mr. Adams wouldn't do that.

16 MR. ADAMS: No.

17 MR. LOVE: Fair enough.

18 (Sidebar concluded.)

19 BY MR. ADAMS:

20 Q. May it please the Court, back to my question, Dr. Pence.

21 You know -- you would agree with me that the Obtryx
22 mesh has been found to be substantially equivalent to other
23 meshes on the market prior to the time that it launched,
24 correct?

25 A. Yes, on the basis of bench and biocompatibility testing

—Pence - Cross - Adams—

1 only.

2 Q. And not only on the basis of that, but -- you know that
3 an entity outside of Boston Scientific has made that
4 determination, correct?

5 MR. LOVE: Objection, Your Honor.

6 THE COURT: That objection is sustained.

7 MR. LOVE: Thank you.

8 MR. ADAMS: All right.

9 THE COURT: And -- I'm sorry. Go ahead.

10 BY MR. ADAMS:

11 Q. And -- now, Dr. Pence, with respect to the testing, the
12 premarket testing on the Obtryx, you would agree with me that
13 there are a number of devices that are in the class of
14 mid-urethral slings with the Obtryx, correct?

15 A. That's correct.

16 Q. And, in fact, the last time we talked, I think you
17 indicated that you had counted and there are approximately 62
18 commercialized mid-urethral slings, correct?

19 A. At least, yes, correct.

20 Q. And you realize that out of those 62 commercialized
21 mid-urethral slings, a very high percentage of those products
22 were never tested in humans prior to being put on the market,
23 correct?

24 A. Yes. And that has been a criticism of that, of those --
25 of the development of those slings, I should say.

—Pence - Cross - Adams—

1 Q. And so, for example, you know that the vast majority of
2 the mid-urethral slings that are on the market today were
3 never subject to any randomized controlled trials prior to the
4 time that they were put on the market; agreed?

5 A. Yes, that is correct.

6 Q. And so with respect to the industry standards, the
7 industry standards really refer to what the majority of the
8 industry is doing with respect to their products, correct?

9 A. The industry standards apply -- they're set up by -- you
10 referred earlier to -- to other bodies and substantial
11 equivalence. Industry standards are -- are, in part,
12 determined by companies.

13 Q. Right. And the vast majority, probably 95 percent of the
14 mid-urethral slings that are not tested before they are put on
15 the market, they would certainly violate your standard, your
16 personal standard, correct?

17 A. Yes, they would. It's not my personal standard. It's a
18 standard based on over 40 years of experience in product
19 development, with the primary focus of patient safety.

20 Q. And of those 62 products, 95 percent or more which are
21 not tested before they are put on the market, they are all
22 being lawfully sold in the United States, correct?

23 A. Yes. And we're seeing major complications arising with
24 them as well.

25 Q. Move to strike everything after "yes," Your Honor.

—Pence - Cross - Adams—

1 THE COURT: That motion is granted, in terms of how
2 the question was phrased.

3 BY MR. ADAMS:

4 Q. Now, Dr. Pence, I believe in your report, you had
5 referred to -- with respect to your opinions that premarket
6 testing should have been done, you had referred to some
7 guidelines that were put out by the Scottish National
8 Institute of Health, correct? Do you recall that?

9 MR. LOVE: Objection, Your Honor. This exceeds the
10 scope of direct examination. It's kind of erratic, I'm not
11 sure where he's going.

12 THE COURT: Any response to the objection, counsel?

13 MR. ADAMS: No, Your Honor. I will --

14 THE COURT: Withdraw?

15 MR. ADAMS: I will withdraw that.

16 THE COURT: All right.

17 BY MR. ADAMS:

18 Q. And, Dr. Pence, you had talked about the safety of
19 polypropylene in the body in your testimony that you gave when
20 discussing that with Mr. Love. Do you recall that?

21 A. Yes.

22 Q. And you're aware of the position statement from January
23 of 2014 by the entity known as AUGS, correct?

24 A. Yes, I am.

25 Q. And I'm going to hand you what has been marked as --

—Pence - Cross - Adams—

1 MR. ADAMS: May I approach, Your Honor?

2 THE COURT: Yes, sir.

3 MR. ADAMS: I'm going to hand you what has been
4 marked as Exhibit 1230.

5 BY MR. ADAMS:

6 Q. Now, you recognize material put out by -- in the *Journal*
7 *of Female Pelvic Medicine and Reconstructive Surgery* as
8 information that is a reliable and authoritative, correct?

9 A. Correct.

10 Q. And, in fact, you've cited a number of different studies
11 from that journal in your report, correct?

12 A. Correct.

13 MR. ADAMS: And if we can -- if we can put up Exhibit
14 1230, Your Honor, just for the record, the -- I'm using this
15 as a learned treatise under 803(18).

16 MR. LOVE: And, Your Honor, I would object on the
17 basis that it's an editorial that was written by consultants
18 for Boston Scientific and done for the purposes of litigation.

19 MR. ADAMS: And, Your Honor, it is published in a
20 journal and counsel's statement is not accurate. But it has
21 been recognized as reliable authority, it's published in the
22 journal, and so I believe I'm entitled to use it under
23 803(18).

24 THE COURT: Let me see it, please.

25 MR. ADAMS: I will.

—Pence - Cross - Adams—

1 THE COURT: Mr. Love, let me bring you to the bench.

2 MR. LOVE: Sure.

3 (The following occurred at sidebar.)

4 MR. ADAMS: Your Honor, first of all, just for
5 reference, this could be confirmed with Kate. This document
6 has been allowed by Judge Goodwin to be used in prior trials
7 under 803(18) after the foundation has been laid that it's
8 reliable and it's authoritative. That's why I asked her those
9 questions.

10 And then, secondly -- and my understanding by reading
11 the transcripts and talking to people is that when he would
12 allow the use of a learned treatise, you can publish it to the
13 jury. The document definitely is not admitted into evidence,
14 but I can read to her certain things.

15 And then the other thing that I would note is that I
16 would appreciate it if speaking objections, like his reference
17 to the Boston Scientific paid consultant on this document,
18 would be made at the bench because I don't think that is an
19 appropriate objection.

20 THE COURT: I understand all that you have offered
21 with respect to how the learned treatise is to be used. My
22 issue, at least initially, is to make that determination.
23 You're saying that this is a document that was prepared for
24 Boston Scientific?

25 MR. LOVE: A couple of things. One, it's an

—Pence - Cross - Adams—

1 editorial. It's not a scientific paper by any stretch of the
2 imagination. These authors here are all consultants to Boston
3 Scientific, Ethicon or other manufacturers, and they
4 specifically testified it was done for litigation purposes.
5 And, second, this has FDA all over it. If it's not properly
6 redacted --

7 MR. ADAMS: I redacted it. I redacted it. That's
8 why there are gaps in that, Your Honor.

9 THE COURT: I'm sorry. I will let you finish.

10 MR. LOVE: And it's not an authoritative source.
11 It's an editorial. It's not based upon science.

12 THE COURT: Mr. Adams, you indicate that Judge
13 Goodwin has allowed this to come in as a learned treatise.

14 MR. ADAMS: Yes.

15 THE COURT: In prior cases?

16 MR. ADAMS: Yes.

17 THE COURT: And that's consistent with your
18 recollection?

19 MR. ADAMS: It is.

20 THE COURT: Mr. --

21 MR. LOVE: I don't have a recollection.

22 MR. ADAMS: And, in fact, they filed a motion in
23 limine on the industry statements which he denied as well.
24 And then I redacted the document because I know, from reading
25 the transcript, that Judge Goodwin demanded that documents be

—Pence - Cross - Adams—

1 redacted with the FDA information.

2 THE COURT: Where was this published? In what
3 journal?

4 MR. ADAMS: The journal down below, Your Honor. It
5 is the *Female Pelvic Medicine and Reconstruction Surgery*
6 *Journal*.

7 THE COURT: All right. Anything further?

8 MR. LOVE: Actually, yes. He is going to use it to
9 suggest that it's a reliable authoritative source and there is
10 no scientific basis for it. It is simply the opinions in an
11 editorial of five consultants for the mesh industry.

12 THE COURT: This document has been referred to as
13 1230. I have reviewed it. I think that, Mr. Love, your
14 characterization of it as an editorial is correct. However,
15 it appears to be part of a *Journal of Female Pelvic Medicine*
16 *and Reconstructive Surgery*, and it's titled at the bottom
17 justification for the position statement. I'm going to permit
18 it under Rule 803.

19 I will be very candid with the parties that I
20 permitted it, in part, because I want to try and make sure
21 that during the course of this trial, that I follow the
22 judge's rulings in terms of the global fairness in all of the
23 cases in which he's going to try. So I'm going to permit it,
24 preserving the plaintiffs' objection and exception to it as a
25 learned treatise.

Pence - Cross - Adams

1 MR. ADAMS: Thank you.

2 (Sidebar concluded.)

3 MR. ADAMS: Okay, Dr. Pence, let's go through this
4 and this is Exhibit 1230. If we could put that up on the
5 screen.

6 (The document was published to the jury.)

7 THE COURT: Mr. Adams, let me interrupt you. Is this
8 a good place that I could give the jury a recess?

9 MR. ADAMS: That would be fine, Your Honor.

10 THE COURT: All right. Ladies and gentlemen, I'm
11 going to give you a recess. While you're out, do not discuss
12 this case among yourselves or permit anyone to discuss it with
13 you or in your presence. You have been in the jury box about
14 two hours now. We will return to the courtroom at
15 approximately 10 minutes till the hour.

16 COURT SERVICES OFFICER: All rise.

17 (The Jury left the courtroom at 3:34 p.m.)

18 (A recess was taken at 3:34 p.m.)

19 THE COURT: I'm sorry. I was told the jury was
20 here. Would you get them, please.

21 COURT SECURITY OFFICER: Yes, ma'am.

22 (Jury entered the courtroom at 3:53 p.m.)

23 THE COURT: You all be seated, ladies and gentlemen.

24 MR. ADAMS: May it please the Court.

25 THE COURT: Mr. Adams, yes, sir.

—Pence - Cross - Adams—

1 BY MR. ADAMS:

2 Q. Dr. Pence, are you ready?

3 A. Yes, I am.

4 Q. Before we took our break we were looking at the statement
5 from the American Urogynecologic Society. You're familiar
6 with that group; correct?

7 A. Yes, I am. I'm a member.

8 Q. And down at the bottom it says that this is put out by
9 that society and also in conjunction with another group or
10 organization for physicians. It's called the Society of
11 Urodynamics Female Pelvic Medicine and Urogenital
12 Reconstruction. Correct?

13 A. SUFU, correct, for short.

14 Q. It's much easier to say SUFU. So, we can see that these
15 are both professional organizations that many doctors in the
16 United States and, in fact, worldwide belong to; correct?

17 A. Correct.

18 Q. And this position statement up at the top, we concede
19 that it says -- if we could blow up that portion, it says,
20 "The polypropylene mesh mid-urethral sling --" and let me stop
21 there. The Obtryx is a polypropylene mid-urethral sling;
22 correct?

23 A. That's correct.

24 Q. It says, "The polypropylene mesh mid-urethral sling is
25 the recognized worldwide standard of care for the surgical

—Pence - Cross - Adams—

1 treatment of stress urinary incontinence. The procedure is
2 safe, effective, and has improved the quality of life for
3 millions of women."

4 Did I read that directly?

5 A. You read that statement correctly, yes.

6 Q. And then when we go down to -- you had voiced some
7 opinions regarding polypropylene. Underneath the section
8 regarding justification for the position statement, it says,
9 "Polypropylene material is safe and effective as a surgical
10 implant. Polypropylene material has been used in most
11 surgical specialties including general surgery, cardiovascular
12 surgery, transplant surgery, ophthalmology --" help me with
13 the pronunciation of this next word.

14 A. Otolaryngology.

15 Q. And what is that?

16 A. Ear, nose, and throat.

17 Q. All right. "It's been also used in gynecology and
18 urology for more than five decades in millions of patients in
19 the United States and the world." Did I read that correctly?

20 A. Yes, but you eliminated the parenthetical "personal
21 communication with manufacturers of polypropylene suture and
22 mesh."

23 Q. Right. And that's right up here. And, in fact, you have
24 seen before -- and I showed the jury a diagram of the human
25 body showing that polypropylene today and going back into the

—Pence - Cross - Adams—

1 1950s is used in various portions all over the body; correct?

2 A. That's correct.

3 Q. And that's what that statement just said; correct?

4 A. Yes.

5 Q. It's been used for five decades all over the parts of the
6 body; correct?

7 A. Yes, in one form or another, that's correct.

8 Q. And the next sentence, it says, "An isolated thread --"
9 "As an isolated thread, polypropylene --" if we can blow that
10 up, the next section just so the jury can read along.

11 Okay. It says, "As an isolated thread, polypropylene
12 is widely used and durable suture material used in a broad
13 range of sizes and applications. As a knitted material,
14 polypropylene mesh is the consensus graft material for
15 augmenting hernia repairs in a number of areas in the body and
16 has significantly and favorably impacted the field of hernia
17 surgery. As a knitted implant for the surgical treatment of
18 SUI, macroporous, monofilament, lightweight polypropylene has
19 demonstrated long-term durability, safety, and efficacy up to
20 17 years."

21 Did I read that correctly?

22 A. You read that correctly, but the last statement I would
23 like to clarify is based on a single study. And that
24 single --

25 Q. My question was: Did I read that correctly?

—Pence - Cross - Adams—

1 A. You read it correctly.

2 Q. Okay. And when it talks about macroporous monofilament
3 polypropylene, that is a term of art to use to describe
4 particular types of polypropylene; correct?

5 A. That's correct.

6 Q. And you know that the polypropylene mesh used in the
7 Obtryx and the Advantage is macroporous monofilament
8 polypropylene mesh; correct?

9 A. It's described as macroporous and monofilament, correct.

10 Q. The next section of this document, if we could blow that
11 up, it says, "The monofilament polypropylene mesh mid-urethral
12 sling is the most extensively studied anti-incontinence
13 procedure in history. A broad evidence base including high
14 quality scientific studies in medical journals in the United
15 States and the world supports the use of the mid-urethral
16 sling as a treatment for stress urinary incontinence. There
17 are greater than 2,000 publications in the scientific
18 literature describing the mid-urethral sling in the treatment
19 of SUI."

20 Did I read that correctly?

21 A. Yes.

22 Q. The last sentence it says, "No other surgical treatment
23 of SUI before or since has been subject to such extensive
24 investigation."

25 Did I read that correctly?

—Pence - Cross - Adams—

1 A. You read that correctly, yes.

2 Q. And then the next paragraph, and we're almost done, the
3 next paragraph is entitled, "Polypropylene mesh mid-urethral
4 slings are the standard of care for the surgical treatment of
5 stress urinary incontinence and represent a great advance in
6 the treatment of this condition for our patients.

7 "Since the publication of numerous level one randomized
8 comparative trials, the mid-urethral sling has become the most
9 common surgical procedure for the treatment of SUI in the
10 United States and the developed world."

11 Did I read that correctly?

12 A. You read that correctly.

13 Q. You know that the Obtryx and the Obtryx II not only are
14 sold lawfully in the United States, but are sold around the
15 world; correct?

16 A. They are.

17 Q. It goes on to say, "This procedure has essentially
18 replaced open and transvaginal suspension surgeries for
19 uncomplicated SUIs. There has been more than 100 surgical
20 procedures developed for the management of SUI and there is
21 now adequate evidence that the mid-urethral sling is
22 associated with less pain, shorter hospitalization, faster
23 return to usual activities, and reduced costs as compared with
24 historic options that have been used to treat SUI over the
25 past century."

—Pence - Cross - Adams—

1 Did I read that correctly?

2 A. Yes, you read that correctly.

3 Q. Now, as part of your research, you looked into the
4 historic options, the surgical options that are available to
5 women if they decide -- or in conjunction with their doctors
6 if they decide that they don't want to use a mid-urethral
7 sling. Correct?

8 A. That's correct, I did.

9 Q. For example, one of the procedures that can be done is
10 the Burch procedure; correct?

11 A. That's correct.

12 Q. Another procedure that can be done is what's called the
13 MMK procedure; correct?

14 A. That's correct.

15 MR. LOVE: Your Honor, objection. This is beyond the
16 scope of direct examination. He's talking about alternative
17 treatments which she clearly didn't testify about.

18 THE COURT: That objection is sustained, Mr. Adams.

19 BY MR. ADAMS:

20 Q. All right. Let's go back to this position
21 statement and finish it out. Down at the bottom it
22 says, "More than three million mid-urethral slings have
23 been placed worldwide and a recent survey indicates that
24 these procedures are used by more than 99 percent of the
25 AUGS members."

—Pence - Cross - Adams—

1 Did I read that correctly?

2 A. Yes, you did.

3 Q. And then finally under the Conclusions, if we could go to
4 that section and blow up that paragraph, it says, "The
5 polypropylene mid-urethral sling has helped millions of women
6 with SUI regain control of their lives by undergoing a simple
7 out-patient procedure that allows them to return to daily life
8 very quickly. With its acknowledged safety and efficacy, it
9 has created an environment for a much larger number of women
10 to have access to treatment. In the past, concerns over
11 failure and invasiveness of surgery caused a substantial
12 percent of incontinent women to live without treatment."

13 The last sentence says, "This procedure is probably the
14 most important advancement in the treatment of SUI in the last
15 50 years and has the full support of our organizations, which
16 are dedicated to improving the lives of women with urinary
17 incontinence."

18 Did I read that correctly?

19 A. Yes, you did.

20 Q. Now, on the first page of this study, it has the list of
21 the individuals that were involved in drafting this statement.
22 Do you see that at the top?

23 A. Yes, I do, but a clarification. This is not a study.
24 This is an editorial.

25 Q. Editorial, fair enough. And the individuals involved are

—Pence - Cross - Adams—

1 Charles Nager, Paul Tulikangas, Dennis Miller, Eric Rovner,
2 and Howard Goldman; correct?

3 A. Yes.

4 Q. And if we look at the back page of this document, there
5 is a disclosure on there -- if we can blow up the position
6 statement box down here, right here. There is a disclosure
7 that one of the persons on the position statement, Dr. Nager,
8 is a principal investigator in the NICHD and NIH Pelvic Floor
9 Disorders Network which is conducting a recommended randomized
10 trial involving transvaginal mesh for prolapse.

11 It goes on to say, "The NICHD/NIH through a public
12 private cooperative arrangement has received partial financial
13 support from Boston Scientific Corporation for this study."
14 Correct?

15 A. That's correct.

16 Q. And then it goes on to say Dennis Miller receives
17 consulting fees and royalties from Boston Scientific for
18 prolapse mesh; correct?

19 A. That's correct.

20 Q. And then it goes on to say that the other individuals who
21 are listed on the front of the editorial, Dr. Tulikangas,
22 Dr. Rovner, Dr. Goldman, have no disclosures; correct?

23 A. That's correct.

24 Q. You're not aware of any association of those individuals
25 with any medical device companies; correct?

—Pence - Cross - Adams—

1 A. I haven't explored those three individuals to see what
2 other, what other connections they might have.

3 Q. And this editorial statement was approved by the Board of
4 Directors of AUGS; correct?

5 A. Yes, many of whom do have an association with industry.

6 Q. And, in fact, there are a number of other industry groups
7 that have put out and adopted this same statement; correct?

8 A. I'm not -- I don't know which organizations you're
9 referring to.

10 Q. Well, were you aware that the Society of Gynecologic
11 Surgeons also have a similar position statement?

12 A. I vaguely recall that, but I don't remember it
13 specifically. If you have it, I would be happy to take a look
14 at it. I have a number of comments about this position
15 statement I would be happy to offer, though.

16 Q. Did you, did you look to see whether this statement has
17 also been adopted by the European Association of Urology?

18 A. No, I didn't, not the European association.

19 Q. What about -- are you aware of a similar position
20 statement by the Royal Australian and New Zealand College of
21 Obstetricians and Gynecologists?

22 A. No.

23 Q. Were you aware of the fact that this statement, or a
24 similar statement has been adopted by the Society of
25 Obstetrics and Gynecology of Canada?

—Pence - Cross - Adams—

1 A. I believe I recall that. However, I'd have to read those
2 statements to see --

3 Q. And you're not here to --

4 A. -- what differences there are.

5 MR. LOVE: Objection, Your Honor, if he could let the
6 witness finish her answer.

7 THE COURT: She does need to finish her answer before
8 you start the next question, Mr. Adams.

9 MR. ADAMS: Yes, ma'am.

10 THE COURT: Ma'am, start and repeat your answer,
11 please. I didn't hear it.

12 THE WITNESS: Okay. Thank you, Your Honor.

13 What I said was in order to say whether or not those
14 position statements are similar, I would need to compare them
15 because there can be sentences in those that may make a
16 substantial difference or have qualifiers or cautionary
17 remarks.

18 BY MR. ADAMS:

19 Q. Now, you mentioned connection to industry in one of
20 your responses dealing with this AUGS statement;
21 correct?

22 A. Yes.

23 Q. Now, in these other organizations that have adopted the
24 same or similar statements, you're not aware of any connection
25 to industry in those organizations; correct?

—Pence - Cross - Adams—

1 A. I can't answer your question because I haven't looked at
2 the authors of those documents and determined whether or not
3 they have industry connections.

4 Q. Let's talk a little bit about the ProteGen product. The
5 ProteGen product was put out by Microvasive in what year,
6 ma'am?

7 A. 1996.

8 Q. And what was Microvasive?

9 A. It was a part of Boston Scientific if I recall correctly.

10 Q. And do you know when Boston Scientific actually purchased
11 Microvasive?

12 A. I don't recall the year it purchased it, no.

13 Q. And the ProteGen, as the jury has heard, was voluntarily
14 removed from the market by Boston Scientific in 1999; correct?

15 A. It was a recall, that's correct.

16 Q. And let's talk about that product. Now, the Obtryx we've
17 already established is a macroporous monofilament mesh;
18 correct?

19 A. It's described as macroporous. It is a monofilament
20 mesh, yes.

21 Q. And the ProteGen, what was the structure or the compound
22 of that material made out of?

23 A. It was a polyester mesh with a bovine, bovine collagen in
24 it as well.

25 Q. And it was also a woven multifilament mesh; correct?

—Pence - Cross - Adams—

1 A. To the best of my recollection, that's correct.

2 Q. And with respect to structures, the Obtryx differs
3 because it is a single-knit monofilament; correct?

4 A. It is a knitted monofilament mesh, correct.

5 Q. And with respect to --

6 A. Polypropylene.

7 Q. -- the actual material, you've already agreed with me
8 that the ProteGen was polyester; correct?

9 A. Yes.

10 Q. And the Obtryx is polypropylene; correct?

11 A. Yes.

12 Q. Did you research the history of how many different types
13 of medical devices were on the market prior to the ProteGen
14 that were made out of polyester?

15 A. I didn't do a tabulation of how many were on there --

16 Q. Were any?

17 A. -- on the market. There are -- with reference to the
18 years, I don't recall. There certainly are other tests on
19 polyester meshes. I don't recall the timing of the marketing
20 of other polyester meshes.

21 Q. And you're aware that -- you say that the ProteGen was
22 actually bovine collagen covered; correct?

23 A. Yes.

24 Q. And the actual process was is that there was pressure
25 injected bovine collagen onto the polyester woven

—Pence - Cross - Adams—

1 multifilament; correct?

2 A. That's correct.

3 Q. And prior to the ProteGen, did your research determine
4 whether there were any other woven multifilament polyester
5 products that had bovine injected collagen on them in the use
6 in the marketplace?

7 A. Prior to the ProteGen?

8 Q. Yes.

9 A. I didn't look at that question specifically.

10 Q. So, you don't know whether -- when people were originally
11 designing the ProteGen whether they had any history at all to
12 go on concerning the biocompatibility of bovine collagen
13 coated polyester; correct?

14 A. The point is that it was a different mesh. And as
15 testified --

16 Q. No, my question, ma'am, if you could answer my question.

17 A. I'm trying to.

18 Q. All right. Let me rephrase it. My simple question is
19 you don't know whether there were any products on the
20 marketplace prior to the ProteGen that were made of polyester
21 that were bovine collagen coated; correct?

22 A. I don't know that specifically, that's correct.

23 Q. And, now, the ProteGen product, that product, how was it
24 anchored inside a woman's body?

25 A. To the best of my recollection, I think it may have been

—Pence - Cross - Adams—

1 sutured. I don't recall definitely. If you have information,
2 I'd be happy to look at it and refresh my memory.

3 Q. Let me try to refresh your memory this way. Do you
4 recall that the ProteGen device actually used what is referred
5 to as bone anchor?

6 A. The bone anchors, yes, that's correct.

7 Q. And bone anchors --

8 A. I do recall now.

9 Q. There's not a single -- in these studies and the position
10 statements that talk about the mid-urethral sling being the
11 gold standard, there's not a single one of those devices that
12 use bone anchors like what was used in the ProteGen; correct?

13 A. That is correct.

14 Q. Now, you've given some testimony on ISO standards. And
15 you'll agree with me, and I think you've agreed with me in the
16 past, that the mesh used with the Obtryx passed all the ISO
17 biocompatibility standards; correct?

18 A. I would not go as far as to say as all the ISO
19 biocompatibility standards. There were a select number of
20 biocompatibility tests that were done, as I mentioned, for the
21 Trelex mesh back in 1992, '93 that were the basis on which --
22 for biocompatibility on which Boston Scientific marketed the
23 Obtryx sling over 10 years later, 11 or 12 years later.

24 Q. And let's look at the ISO standards. And you're familiar
25 with the ISO standard --

—Pence - Cross - Adams—

1 A. Yes, I am.

2 Q. -- 10993-1. I'm going to hand you what has been marked
3 as 1059. And 1059 is a collection of the international
4 standard which is referred to as ISO 10993-1. Correct?

5 A. That's correct.

6 Q. And, obviously, you recognize this to be the actual
7 standard that we've been referring to. And you recognize that
8 this is a reliable standard from an authoritative document?

9 A. It's part one of the standard.

10 Q. If we could put the standard up just so the jury
11 understands. These standards, we talk about compliance with
12 ISO.

13 THE COURT: Counsel, is that something that has been
14 admitted into evidence?

15 MR. ADAMS: No, and I would rely upon it as a learned
16 treatise.

17 MR. LOVE: Your Honor, with respect to my objection,
18 I would object. This is well beyond the scope of my direct
19 examination.

20 THE COURT: It is well beyond the scope of direct
21 examination and I will sustain that objection. And I'm going
22 to ask you all again not to put anything up on that screen for
23 the jury until I admit it into evidence.

24 MR. ADAMS: Will do, Your Honor. I thought I had
25 laid the foundation for authoritative treatise. And I believe

—Pence - Cross - Adams—

1 that Mr. Love did discuss biocompatibility testing which are
2 done pursuant to the standard. That's why I was going into
3 it. So, it was within the scope.

4 THE COURT: I think that we're far beyond testing and
5 I'm going to sustain the objection.

6 MR. ADAMS: Understood, Your Honor. I'll move on.

7 THE COURT: They made every effort on direct
8 examination to limit her testimony to her opinion with respect
9 to testing and I think that's where we need to stay for cross.

10 MR. ADAMS: Certainly, Your Honor.

11 BY MR. ADAMS:

12 Q. Let's move on from that, Dr. Pence, to the last
13 series of questions. Did you review any of the
14 depositions of the doctors who actually implanted the
15 Obtryx in any of the four ladies that are involved in
16 this case?

17 A. No, I did not.

18 Q. And, so, you don't know what their personal experience
19 has been concerning the safety and effectiveness of the Obtryx
20 that they've observed in their practice; correct?

21 MR. LOVE: Objection again, Your Honor, beyond the
22 scope of her testimony. She's not a medical doctor, nor is
23 she commenting on their standard of care or what they do or
24 don't do.

25 THE COURT: And I sustain that objection.

—Pence - Redirect - Love—

1 MR. ADAMS: All right.

2 BY MR. ADAMS:

3 Q. No other questions, Dr. Pence. Thank you.

4 A. Thank you.

5 THE COURT: Is there redirect of this witness?

6 MR. LOVE: It will be brief, five, ten minutes tops.

7 THE COURT: You promise?

8 MR. LOVE: I promise. May I proceed, Your Honor?

9 THE COURT: Yes, sir.

10 REDIRECT EXAMINATION BY MR. LOVE:

11 Q. Hello again.

12 A. Hello again.

13 Q. May we bring up Exhibit 1004, the MSDS. Just a few quick
14 questions I want to jump around. I just want to make sure
15 that we're on the same page as to some topics that were
16 covered in the cross-examination.

17 A. Okay.

18 Q. Let's go back to ProteGen real quick. What did Boston
19 Scientific conclude internally with respect to human testing
20 on future sling materials --

21 A. That --

22 Q. -- based upon the withdrawal of the ProteGen product?

23 A. That human testing needed to be done to ensure the safety
24 of a product prior to marketing.

25 Q. Okay. Whether it's polypropylene or some other sling,

—Pence - Redirect - Love—

1 Boston Scientific concluded that with respect to this company,
2 we're going to what?

3 MR. ADAMS: Objection, Your Honor. This is leading.

4 BY MR. LOVE:

5 Q. What did Boston Scientific --

6 THE COURT: Well, --

7 MR. LOVE: Excuse me. I'm sorry.

8 THE COURT: Let me rule on it.

9 Counsel, I think with respect to an expert witness,
10 leading is permissible. I'm going to overrule the objection
11 in the interest of time and given the subject matter of where
12 we are, Mr. Adams.

13 BY MR. LOVE:

14 Q. Irrespective --

15 THE COURT: Go ahead, please.

16 MR. LOVE: Thank you, Your Honor. I apologize.

17 BY MR. LOVE:

18 Q. With respect to future sling polypropylene
19 materials, whether it's polypropylene or some other
20 material, what did Boston Scientific say they were going
21 to do in the future?

22 A. They were going to do clinical trials in a variety of
23 clinical situations.

24 Q. Okay. Let's pull up the polypropylene slide. And can we
25 click -- while he's getting that ready, let's just keep moving

—Pence - Redirect - Love—

1 on. You talked about a class of mid-urethral slings with Mr.
2 Adams. Do you recall that testimony?

3 A. Yes.

4 Q. And he said that there were like 62 or something other
5 mid-urethral slings in this category where some of them didn't
6 have human testing as well. Do you remember that testimony?

7 A. Yes, I do.

8 Q. What was different about the Obtryx sling that made
9 testing a requirement?

10 A. Several things. First of all, the ProteGen sling, as
11 we've talked about, which they had already had experience with
12 and withdrew from the market because of safety problems and
13 problems as well with usage of it by physicians. And, so,
14 they had that experience and had included, as we were just
15 saying, internally that they realized they needed to do
16 clinical testing in the future.

17 The de-tanged mid section of the Obtryx sling was
18 different. That needed to be examined.

19 The other very important point is that because there
20 hadn't been -- in part because there had been no clinical
21 trials done prior to marketing of many of these slings,
22 particularly long-term, there were even, even post-marketing
23 when clinical trials were done. There were short-term
24 results. But as long-term data started -- longer term, I
25 should say, data started to come in because there's still a

—Pence - Redirect - Love—

1 lack of adequate long-term data, serious complications began
2 to be seen.

3 And those type -- and serious complications were
4 available in the literature at the time of development of the
5 Obtryx sling which, again, was a reason for them to test the
6 Obtryx sling to see if it was going to be safe for use.

7 Q. Perfect, perfect. So, there were differences between the
8 Obtryx sling and the other mid-urethral slings?

9 A. That's correct.

10 Q. Okay. Let's go to the MSDS if we can real quick. Let's
11 go ahead and pull up -- do you have the PowerPoint? There you
12 go. Perfect. Okay.

13 Now, there were some questions about this that in the
14 '90s the MSDS didn't contain this warning. Do you remember
15 that line of questioning?

16 A. Yes, I do.

17 Q. But it did in 2004; right?

18 A. That's correct.

19 Q. Okay. Because there's no warning in the '90s, is it okay
20 to ignore it when it appears in 2004?

21 A. No.

22 Q. Okay. Was there any scientific basis to conclude that
23 polypropylene was safe for permanent human implantation in the
24 pelvic region?

25 A. No, there was not.

—Pence - Redirect - Love—

1 Q. Okay. Let's go to the last page of the particular MSDS,
2 if you'll go ahead and highlight that.

3 "This information is furnished upon condition that the
4 person receiving it shall make his own determination of the
5 suitability of the material for his particular purpose."

6 What does that tell the reader or the purchaser of the
7 polypropylene material in 2004?

8 A. It's telling the purchaser, in this case Boston
9 Scientific, that they needed to determine the suitability of
10 the product for permanent implantation. And, in fact, there
11 was a contract, the contract for sale of the polypropylene for
12 use in Boston Scientific slings also stated that to the best
13 of my recollection.

14 Q. Okay. You mentioned a Ms. Rao, Doreen Rao. She's going
15 to testify tomorrow here. And he mentioned that she did an
16 investigation herself and determined that the language had no
17 scientific basis; right?

18 A. Yes.

19 Q. Okay. Is there any scientific evidence establishing that
20 polypropylene is safe in the pelvic region at the time Ms. Rao
21 did her investigation?

22 A. No.

23 Q. Okay. I think he mentioned something about it was done
24 for legal purposes, legal language. Do you understand that
25 Chevron Phillips was concerned about these very types of

—Pence - Redirect - Love—

1 lawsuits and that's why they required the language?

2 A. That's correct.

3 MR. ADAMS: Lack of foundation and speculation, Your
4 Honor.

5 THE COURT: There is an objection, counsel. Do you
6 want to respond to it?

7 BY MR. LOVE:

8 Q. Are you aware of why the legal language was --

9 THE COURT: Is there a response to the objection?

10 MR. LOVE: I can rephrase my question, Your Honor.

11 THE COURT: He is withdrawing that question, Mr.
12 Adams, and asking another one. Go ahead, please.

13 MR. ADAMS: Thank you, Your Honor.

14 BY MR. LOVE:

15 Q. Are you aware of why the language was added?

16 A. I have -- some of the information that I've reviewed has
17 indicated it was because of product liability concerns.

18 Q. Okay. Let's talk about that AUGS statement again.

19 If you could, Mr. Adams, if your technical person could
20 assist us.

21 MR. ADAMS: Sure.

22 MR. LOVE: If you could pull that up and we need to
23 make a switch here real quick. I'm almost done. I've just
24 got two or three questions on this just to make sure we're on
25 the same page.

—Pence - Redirect - Love—

1 (Pause)

2 MR. LOVE: I think it's 1230.

3 MR. ADAMS: You're right. It is 1230.

4 MR. LOVE: Perfect. Thank you very much.

5 BY MR. LOVE:

6 Q. Okay. First of all, this is an editorial; right?

7 A. That's correct.

8 Q. This is an opinion piece by these five guys?

9 A. That's correct.

10 Q. Okay. This is not based upon a scientific analysis of
11 the safety literature that's available with respect to the
12 Obtryx sling, for instance?

13 A. That's correct.

14 Q. It's not a scientific piece that's based upon an analysis
15 of all the available scientific literature that's available on
16 mesh polypropylene?

17 A. That's correct.

18 Q. Okay. This is done by Boston Scientific consultants who
19 write an editorial about what they think is appropriate for
20 mid-urethral slings?

21 A. Yes, two of the authors, that's correct, had a connection
22 with Boston Scientific. And one of them, Dr. Miller, was
23 receiving royalties for his part in developing another mesh
24 product.

25 Q. Another mesh product?

—Pence - Redirect - Love—

1 A. Of Boston Scientific.

2 Q. Okay, okay. Let's go to the second page if we can. I
3 know there was a statement you wanted to make a comment on and
4 I want to -- if we can go to the second page. And I believe
5 it's that -- if you could highlight this first top paragraph
6 on the left. Perfect. All right, great. All right.

7 BY MR. LOVE:

8 Q. So, that statement was read to you about a 17-year
9 study that was done?

10 A. Yes.

11 Q. What was the product in that 17-year study?

12 A. That was the -- that was the original retropubic sling
13 developed by Ulmsten and ultimately marketed by Ethicon. And
14 the --

15 Q. So, it's an Ethicon product, which is J&J I think; right?

16 A. That's correct.

17 Q. Johnson & Johnson?

18 A. That's correct.

19 Q. It's called a TVT?

20 A. That's correct.

21 Q. All right. So, it's a different product?

22 A. That's correct.

23 Q. Made by a different company?

24 A. That's correct.

25 Q. And, so, does it deal with the Obtryx at all?

—Pence - Redirect - Love—

1 A. No. In fact, the insertion route is totally different as
2 well.

3 Q. Were there any Obtryx slings involved in that study?

4 A. No.

5 Q. Okay. Now, you said you wanted -- you had a few comments
6 when Mr. Adams was talking to you about this, but you didn't
7 get an opportunity to talk about them. What are your comments
8 about this AUGS position paper editorial?

9 A. Several. First, with that statement we were just talking
10 about with the durability, safety, and efficacy up to 17
11 years. That 17-year review was on a small number of patients
12 and was flawed because there were a number of patients that
13 were lost follow-up. And, so, the 17-year safety, efficacy,
14 durability was not known for that patient.

15 And from my experience of many years conducting
16 clinical trials, when patients are not available for giving --
17 when they're lost follow-up, they're not available for
18 ascertaining what their long-term durability is or safety or
19 efficacy. You don't know if it's because the product really
20 didn't work very well for them or because they liked it.

21 So, there are a lot of open questions there.

22 Q. Let's just get to the chase. Did that 17-year study, was
23 it done on Obtryx slings?

24 A. No.

25 Q. Okay. It was done on a different product, TVT?

—Pence - Redirect - Love—

1 A. That's correct.

2 Q. Did this TVT 17-year study, did it have de-tanged edges?

3 A. No.

4 Q. Okay. Different product, different design, different
5 company.

6 A. That's correct.

7 Q. All right. Any other comments on the AUGS statement that
8 you need to clarify?

9 A. Yes, a number. It's not fair and balanced. It discusses
10 the 2000 publications and it discusses that the scientific
11 literature provides evidence of safety and effectiveness. And
12 the literature is very mixed. And there are authoritative
13 statements that the literature is lacking randomized
14 controlled trials that are long-term. The data is mostly
15 short-term.

16 As this statement was being written, there were a
17 number of publications coming out in that time frame showing
18 serious complications with mid-urethral slings.

19 Q. Okay. Listen, you've been up there a long time today. I
20 appreciate your time and your patience.

21 A. Thank you.

22 THE COURT: You can step down, ma'am.

23 THE WITNESS: Thank you, Your Honor.

24 THE COURT: Call your next witness.

25 MR. LOVE: Your Honor, at this time, we would call

—Miragliuolo - By Video—

1 Rob Miragliuolo. He is the Vice President of Regulatory
2 Affairs and his deposition time is 21 minutes.

3 (The videotaped deposition of Robert Miragliuolo was
4 played for the jury.)

5 MR. MONSOUR: Your Honor, that concludes the offer
6 for Mr. Miragliuolo. At this point in time, it's 10 till.
7 We've got two videos --

8 MR. STRONGMAN: Boston has a two-minute counter.

9 MR. MONSOUR: I'm sorry. I thought yours was
10 included.

11 MR. STRONGMAN: But it's short.

12 MR. MONSOUR: Okay.

13 (The videotaped deposition of Robert Miragliuolo
14 continued to be played for the jury.)

15 MR. STRONGMAN: That concludes Boston Scientific's.

16 THE COURT: All right. Thank you.

17 Ladies and gentlemen of the jury, I'm going to
18 release you for your evening recess. While you're out, do not
19 discuss the case among yourselves or permit anyone to discuss
20 it with you or in your presence. And remember that you are
21 not to listen to, view, or read any news media coverage that
22 there might be of the trial.

23 Have a good, restful evening and I will see you at
24 9:00 a.m. tomorrow morning.

25 Yes, ma'am.

—Colloquy—

1 A JUROR: We just have court tomorrow and Wednesday;
2 correct? We don't have it Thursday and Friday.

3 THE COURT: Yes, ma'am.

4 A JUROR: Thank you.

5 THE COURT: You're welcome. You all have a good
6 evening.

7 (Jury left the courtroom at 4:52 p.m.)

8 THE COURT: Mr. Adams, you made an objection during
9 the course of Dr. Pence's testimony. You had asked her
10 regarding whether or not she, her research had -- if she had
11 researched to see if the same component had been used. I --
12 she answered you. You then asked that I strike the remainder
13 of her answer which I refused to do, and I told you that I
14 would address it at the bench if necessary.

15 I simply wanted to place on the record her answer
16 went to the effect, and I don't quote her exactly, that they
17 were not marketing the product, but marketing the Obtryx sling
18 and it needed to be tested in its current composition. When
19 she referred to product, I understood that she was referring
20 to the composition, not the Obtryx itself.

21 It was that portion of the answer that she did not
22 answer to you "yes" or "no" as to whether or not she had
23 researched to see if this, the current Obtryx was made out of
24 the same component. She indicated it did not matter to her
25 because they were not marketing the product but marketing the

—Colloquy—

1 Obtryx sling and it needed to be tested in its current
2 composition to determine if appropriate to be marketed.

3 I denied your motion to strike the, that portion of
4 her answer. And I did so believing that she was answering you
5 "no" without specifically saying "no" and then giving her
6 explanation as to why. And I simply wanted to place that on
7 the record for you.

8 Are there other matters that need to be addressed
9 here this evening?

10 MR. MONSOUR: I would like to give you the four
11 points memo. I think you admitted the first page. I was not
12 clear whether you entered the first page or the entirety of
13 the document.

14 MR. ADAMS: Only the first page was offered.

15 MR. MONSOUR: So, what I did, Your Honor, pursuant to
16 our discussion earlier, is I have marked through in a pen so
17 you can see what's being marked out underneath pretty clearly
18 the references that have the FDA. And I was just going to
19 hand you this and let you look at it. And maybe we could
20 address it real quickly in the morning if Mr. Adams had any
21 objections.

22 THE COURT: We can address it now. I believe that I
23 indicated to you that I wanted to see your redactions and then
24 I would make a ruling on the admissibility of the document.

25 MR. MONSOUR: Thank you, Your Honor.

—Colloquy—

1 THE COURT: And have you shared this with Mr. Adams
2 as well?

3 MR. MONSOUR: Yes.

4 MR. ADAMS: He has. And I guess my position on it,
5 Your Honor, I think we got into this whole line of -- well,
6 the whole issue on this document is -- I believe the Court's
7 ruling is that it's relevant to show that Boston Scientific
8 recognized, if we look at the last bullet point on the first
9 page, recognized that after the ProteGen experience we needed
10 to do future clinical data.

11 The plaintiffs have already got into evidence that
12 there was a recall, and I don't think that the rest of the
13 document is -- well, under a 403 analysis I don't think you
14 need to admit this document.

15 So, for example, it asks questions about, "Why was
16 the ProteGen recalled?" That's really irrelevant. They've
17 already proven their point that it was recalled. And, again,
18 the message on the key take-away that we would do future
19 performance, they've made that point too.

20 Again, the problem with redacting the FDA is the
21 recall was done pursuant -- well, the recall is tied to FDA
22 action. And, so, that's what I think makes the rest of the
23 document very prejudicial.

24 And, again, I think that the points that, for which
25 the document was admitted have already been made by the first

—Colloquy—

1 page of the document that was offered by Mr. Love. That's all
2 I'll say on it.

3 THE COURT: Mr. Monsour.

4 MR. MONSOUR: My response to that, Your Honor, would
5 be -- I talked earlier and I'm not going to waste your time,
6 the basis for admissibility of the ProteGen issue.

7 This document is a little different. This document
8 talks about their conduct before with slings and sets up the
9 subsequent conduct.

10 If you look through that document, one of the claims
11 that we have in this case is a claim for gross negligence,
12 punitive damages. If you look at that document, you will see
13 that with regard to that document, they recall this product.
14 They say they're going to do -- they are going to do future
15 clinical studies on sling materials.

16 But then they also say in that document, "We deny
17 that this -- we deny that this product is faulty and we will
18 defend it in lawsuits." It's the same thing they're doing
19 here.

20 And we have a claim for gross negligence in this
21 case. And the motion for summary judgment on that claim was
22 denied. Therefore, we are allowed to proffer evidence of
23 gross negligence and conscious indifference in this case.

24 And because we are allowed to offer that, this
25 document specifically shows a conscious disregard, a

—Colloquy—

1 continuing conscious disregard by the company for the safety
2 of the women that its products are intended for. And that is
3 one of the primary bases that I would like this document
4 entered, Your Honor.

5 THE COURT: All right, counsel, I have previously
6 ruled that the information contained in the document went to
7 the defendant's knowledge and was probative on the issue of
8 punitive damages.

9 I have reviewed it in the position that it was given
10 to me, or the condition that it was given to me with the
11 proposed redactions in it. I believe that those redactions
12 take care of the issues outlined in Judge Goodwin's pre-trial
13 orders. And I am, therefore, going to admit the document in
14 its entirety, preserving, Mr. Adams, your objection and
15 exception with the redactions done.

16 Mr. Monsour.

17 MR. MONSOUR: Yes. If you will give that to me, Your
18 Honor, I will get a clean version tomorrow and we will proffer
19 it first thing.

20 THE COURT: I was hoping to take it home with me.

21 Anything further you all want to cover this evening?

22 MR. ADAMS: No. And I appreciated your clarification
23 on my objection on Dr. Pence. And I will also acknowledge
24 that my objection should have been better. I should have
25 moved -- I should have said, "Objection, nonresponsive." And

—Colloquy—

1 I will do that in the future because I, I think that might
2 have caused the confusion by the Court. So, I apologize.

3 THE COURT: Well, to be perfectly candid with you,
4 that is how I construed it. But because I believe she
5 impliedly answered "no" when she gave the explanation, that
6 was my reason for not striking the answer as you requested.

7 MR. ADAMS: Very good.

8 THE COURT: You all have a good, restful evening and
9 I'll see you at 9:00 a.m. tomorrow.

10 MR. MONSOUR: Thank you, Your Honor.

11 (Trial recessed at 5:00 p.m.)

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REPORTERS' CERTIFICATE

Carol Farrell, CRR, RMR, CCP, RPR, RSA, Official Court Reporter of the United States District Court for the Southern District of West Virginia, and **Lisa A. Cook, RPR, RMR, CRR, FCRR**, do hereby certify that the foregoing is a true and accurate transcript, to the best of our ability, of the proceedings as taken stenographically by and before us at the time, place, and on the date hereinbefore set forth.

/S/ Carol Farrell, CRR, RMR, CCP, RPR

11/03/14

Court Reporter

Date

/S/ Lisa A. Cook, RPR, RMR, CRR, FCRR

11/03/14

Court Reporter

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